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WEIGHT REDUCTION PRODUCTS AND PLANS

HEARINGS

BEFORE THE

PERMANENT

SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON

GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

NINETY-NINTH CONGRESS

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WEIGHT REDUCTION PRODUCTS AND PLANS

TUESDAY, MAY 14, 1985

U.S. Senate,
Permanent Subcommittee on Investigations,
Committee on Governmental Affairs,
Washington, DC.

The subcommittee met at 10 a.m., in room SD-342, Dirksen Senate Office Building, under authority of S. Res. 145, section 13, dated May 3, 1985, Hon. William V. Roth, Jr. (chairman of the subcommittee) presiding.

Members of the subcommittee present: Senator William V. Roth, Jr., Republican, Delaware; Senator Warren B. Rudman, Republican, New Hampshire; Senator William S. Cohen, Republican, Maine; Senator Sam Nunn, Democrat, Georgia; Senator John Glenn, Democrat, Ohio; and Senator Albert Gore, Jr., Democrat, Tennessee.

Members of the professional staff present: Daniel F. Rinzel, chief counsel; Eleanore J. Hill, chief counsel to the minority; Katherine Bidden, chief clerk; Leonard Willis, minority investigator; Paul Barbadoro, Barbara Cart, Howard Shapiro, and Barbara Kammerman, staff counsel; Carla Martin and Cindy Comstock, staff assistants; Sarah Presgrave, executive assistant to the chief counsel of the majority; and Charles Osolin, press secretary.

[Senators present at the convening of the hearing: Senators Roth and Glenn.]

OPENING STATEMENT OF CHAIRMAN ROTH

Chairman Roth. The subcommittee will please be in order.

This morning, the Permanent Subcommittee on Investigations begins its hearings on weight reduction products and plans, which are the result of a 5-month investigation.

Weight reduction products have become a multibillion dollar per year industry, fueled by the public's increasing desire for fitness and slimness. As demonstrated by many studies, a large segment of the public is overweight to some extent, and some persons are extremely and unhealthfully overweight. Most recently, a study by the National Institutes of Health has concluded that obesity should be classified as a disease.

It is clear that some potential diet customers are vulnerable customers willing to try multiple plans and products until one is successful, even including unproven and, frankly, seemingly impossible products. They are also often embarrassed to admit a product does not work, perhaps because they feel it works for others but not for them, or because the cost was not very high.

I want to make it perfectly clear from the start that we intend to look at different categories of diet products, and these categories should not be linked together in any way.

For example, there are products which, according to almost all medical and nutritional experts, have no efficacy at all for weight loss. These patently fraudulent products include miracle pills, creams, tinted sunglasses, plastic ear forms, and other similar products.

Over 30,000 specially fitted ear forms were sold in less than 2 years. One mail order marketer of "Dream-Away" pills was allegedly receiving $90,000 worth of orders daily at one point. According to the Post Office, another mail order marketer was picking up daily mail deliveries in a Brinks truck. These products are big business. Frankly, I find it hard to believe that people purchase these items, and I do not intend to spend a great deal of time discussing them during these 2 days. But I do know that many Americans do purchase these products because they are desperate to lose weight, and in doing so, they are reducing, frankly, nothing but the contents of their pocketbooks and checkbooks.

These fraudulent products must be distinguished from the very low calorie products which we intend to review in much greater depth. The very low calorie products can cause significant weight losses in many people, and have done so. My principal concern with these very low calorie products is what the Food and Drug Administration is doing and what it is not doing, particularly when serious questions have been raised both within the FDA and outside this agency about the safety of such products.

I do not know if these products are inherently unsafe, nor has our extensive investigation reached any definitive conclusion regarding the safety of products such as Herbalife. But I do know that there are enough questions being raised by the medical community, by former users and by the media to warrant a closer examination by FDA.

We are dealing with a multibillion-dollar industry which produces items ingested into the human body. Yet, for some reason, the FDA has been reticent to involve itself in low-calorie diets. I want to know why because I think the public deserves to know conclusively about the safety of individual products now in the marketplace.

Perhaps it would be appropriate at this time to comment upon the subcommittee's review of Herbalife due to what may be an unprecedented reaction to our inquiry.

A significant amount of testimony during the next 2 days will concern Herbalife and its products. This situation has arisen in part because of Herbalife's size and phenomenal growth, with projected retail sales in 1985 of $1 billion.

Further, significant questions regarding Herbalife products and their method of direct sales marketing have been raised by numerous media outlets, medical experts and Federal and State agencies, including the FDA and the State of California, which recently filed a lawsuit against Herbalife.

However, I have noted with great interest that very large numbers of phone calls and letters from individuals in Delaware and across the country have been generated as a result of these hearings, individuals who are very satisfied with the Herbalife products and say that they have lost large amounts of weight.

Tomorrow we hope to receive answers to many of the questions which have been raised from Mark Hughes, the founder of Herbalife, and from Vaughn Feather, the president of Cambridge, another leading very low calorie diet manufacturer.

The subcommittee is concerned about reports of illnesses and deaths associated with the use of very low calorie diets. In the cases investigated by the committee, it is difficult, if not impossible, to find direct causation. But unexplained deaths and illnesses have occurred that may be associated with the diets, and more scrutiny is needed to ensure safety.

As mentioned before, the primary agency regarding the issues of safety and efficacy of diet products is FDA. The Commissioner of the Food and Drug Administration, Dr. Frank Young, will be appearing as a witness tomorrow morning, and I intend to ask him exactly how far FDA's authority reaches and what the FDA is doing and what they are not doing in this area.

I want to make it clear the purpose of these hearings is not to get Herbalife or any other product. The purpose is to find out if the public is being adequately protected when it buys and consumes diet products.

[At this point in the hearing, Senator Gore entered the hearing room.]

Chairman ROTH. We want to see the fraudulent separated from the effective; the dangerous from the safe. And I would hope that the FDA and the diet industry shares our goals, too. Senator Glenn?

OPENING STATEMENT OF SENATOR GLENN

Senator GLENN. Thank you very much, Mr. Chairman. I am pleased the Senate Permanent Subcommittee on Investigations is holding this hearing to examine the safety, the efficacy and the marketing of weight reduction products.

As the chairman already mentioned, this is a $1 billion business. Unfortunately, this marketing success is too often due to misleading or false advertising gimmicks, rather than the efficiency of the products themselves. So the economic losses to consumers are significant, but even more distressing is that some of these products may be potentially hazardous to the user's health.

Let me be very, very clear about one thing. I am not here to deride or discredit any particular product or any particular weight reduction plan merely because I personally may find it hard to accept their advertising claims. Many people in my home State of Ohio have apparently been alerted of these hearings and had the opinion expressed to them that these hearings were aimed at one particular product and that is certainly not my intention. It is to look at the whole field and see what the problem is. In my view, the U.S. Government has no business playing Big Brother. All Americans should have the right to choose any diet plan they wish so long as the advertising claims of those plans are not fraudulent, Federal rules and regulations are being adhered to and the products do not constitute a public health hazard.

This morning I am here to gather facts and information which I hope would keep consumers from being ripped off or even seriously injured by unscrupulous companies.

[At this point in the hearing, Senator Cohen entered the hearing room.]

Senator GLENN. The diet plans and products we are examining today are those generally not sold at the local corner drugstore. Instead, most are sold through the mail or directly to the consumer through the use of multilevel marketing techniques.

The mail-order industry, of course, offers a convenient, easy and accessible form of shopping for many of us. The majority of mail order firms are legitimate business enterprises, but today we will learn about some of them, the fraudulent practices that some firms may use to take ruthless advantage of our citizens.

How many times have we read attractive advertisements in magazines and newspapers promising quick and easy weight loss, land sales, time-sharing condominiums, or miracle cures for arthritis and other disorders? I can think—all of us, probably everybody in the room almost—would question the legitimacy of a pill whose promoters allow us to "dream away" excess poundage. Like many Americans, I have been fighting the "battle of the bulge" most of my life. If I could "dream away" fat, I would not be sitting here now; I would go away and take a nap someplace, I guess. [Laughter].

I am appalled by a diet plan that insists you can alleviate hunger pangs by pressing an earring-like device and squeeze it 10 times before eating. I do not think you have to be a genius to understand products like those are probably phony, a waste of money and there may be some psychological tie-in to doing something like that.

I agree with the potential of that, but people undoubtedly are being ripped off by such claims.

Worst of all, these proposals invade our homes, not through our doors or windows as a burglar would, but through the mailbox. Each year, honest citizens lose millions of dollars to these con artists.

I would add, this is not my first involvement with a hearing of this type. Several years ago, the Senate Special Committee on Aging, on which I serve as a senior Democratic member, investigated some of this growing problem. And I, in fact, had a bill in back in the late 1970's that included much of what was later passed in a 1983 bill which Congress passed, the Mail Order Consumer Protection Amendments of 1983. I cosponsored that and much of what I had in the original legislation was included in those amendments of 1983. And I have been pleased to learn that the Postmaster General, with the new law's enforcement and investigative power, is moving aggressively against the larger and most unscrupulous mail order promoters. So for this important accomplishment, I commend the Postal Inspection Service and look forward to continued progress in this important area.

Part of the problem is just in determining what is a food and what is a drug. We have yet to really clearly define that differentiation. But, in my judgment, the possible health hazards associated with the use of these diets are of even greater concern.

The Food and Drug Administration is responsible for monitoring the safety and efficacy of the diverse and numerous diet-reduction products currently on the market.

In the past week, I heard from many Ohio residents who have benefited from these diet programs. At the same time, I have also learned of a number of individual cases of health complications associated with the use of different diets. So let me just reiterate what I said at the outset. The purpose of this hearing is to find out if our citizens are being adequately protected from questionable diet products by the Federal Government. If not, to formulate possible legislative remedies to alleviate this situation. I am delighted we have representatives of various sides, on all sides of this issue, and I look forward to hearing from health experts, marketers, users of diet products, individuals who experienced positive and/or negative consequences of these diets, and representatives of the FDA. I am sure their information will be very helpful to us in our deliberations. Thank you, Mr. Chairman.

Chairman ROTH. Thank you, Senator Glenn. Senator Gore?

OPENING STATEMENT OF SENATOR GORE

Senator GORE. Thank you very much, Mr. Chairman. I would like to congratulate you for convening these important and necessary proceedings. Diets affect millions of Americans, and it is often the case we need that extra help in disciplining ourselves to lose weight. However, it is also true that the laws in our country are intended to protect the public's health and ensure that the public has a right to know what it is consuming.

It is also the law that when a claim is made in an advertisement, the public has a right to know and the company has an obligation to ensure that the claims being made about the products are, in fact, true. Thus, I am troubled, Mr. Chairman, that some preliminary evidence presented to this subcommittee has raised grave questions about the efficacy and safety of some of the products examined.

I also have questions as to whether Government agencies, especially the Food and Drug Administration, has carried out their responsibilities to protect the public's health.

I look forward to these 2 days of hearings. I trust they will be fair, vigorous and thorough and look forward to participating in them.

Chairman ROTH. Thank you. Senator Cohen?

Senator COHEN. No comment.

Chairman ROTH. At this time, we will call upon Howard Shapiro to make a statement. He is a member of the Permanent Subcommittee on Investigations and according to the rules of the subcommittee, all witnesses will be sworn.

Do you swear the testimony you will give before this subcommittee will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. SHAPIRO. I do.

Chairman ROTH. Please proceed.

TESTIMONY OF HOWARD L. SHAPIRO, STAFF COUNSEL, PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

Mr. SHAPIRO. Thank you, Mr. Chairman. I would like to just make some brief introductory remarks to place this investigation and this hearing into perspective. I would like to have my entire statement entered into the record, and I plan to summarize it here this morning.

Chairman ROTH. Without objection.

Mr. SHAPIRO. The subcommittee's investigation of weight reduction products and plans began in January of this year. The staff began the investigation by contacting the three primary agencies involved in this area; that being the FDA, the Federal Trade Commission and the Postal Inspection Service. We did this to gather background information on jurisdiction and authority and to discuss recent and pending investigations and cases.

Agency file reviews were also conducted, reviews which encompassed scientific and medical reports, investigative files, and complaints received from diet product consumers, concerning both economic loss as well as adverse physical reactions. These file reviews also enabled the staff to identify the major types of diet products being marketed and the major manufacturers and marketers in the country.

Numerous contacts were then made with manufacturers, marketers and consumers. In some instances, information was obtained through the issuance of subpoenas. The subcommittee purchased a number of diet products through the mails and obtained other products from consumers. Scientific and medical experts were also consulted to gather information on the safety and efficacy of some products and to describe how the body acts to weight loss.

As you mentioned, our investigation concentrated on two basic categories of diet products. The first category are those products which appear to be worthless or virtually worthless. These include, as you mentioned, all types of creams, pills, and devices.

We purchased for $19.95 this plastic Acu-Ring, which is a small piece of plastic. We got it from a mail order company in Dallas, and we received with it an instruction sheet which I would like to place into the hearing record.

Chairman ROTH. This will be included in the record as exhibit No. 1.

[See exhibit No. 1 on page 279.]

Mr. SHAPIRO. The instructions state whenever I feel the urge to overeat, I should put this on my ear and squeeze it 10 times in succession—as Senator Glenn mentioned—and then I can decide at that point if I can forego the food, and if so, I can set aside the food until I want it.

The instruction sheet also includes a recommended food program which is described as an essential part of the diet plan, and this basically is the way the manufacturers, such as these, avoid enforcement actions based upon alleged deceptive advertising, by devoting a very small portion of their instructions or advertising to an explanation of the overall diet plan.

This small print would normally state the products only work as advertised if the accompanying plan is followed and this plan is normally a basic menu suggestion for perhaps a 1,200-calorie-per-day diet.

The reason for including this plan in the small print is very simple, because the only way to lose weight, as I am sure our experts will tell us, is to reduce net caloric intake. Wearing this plastic ear form cannot cause weight reduction. Whether wearing this plastic ear form can cause appetite suppression will be a question that our experts can answer.

But many diet product manufacturers deceive the customer by making the so-called diet plan a very small part of their ads and leaving the overall impression that the products do the work.

Another example would be these ads we have here on the easels from a mail-order marketer from Canton, OH. We can all see the headlines promise incredible results. The product is basically a pill, and in the lower left-hand corner of each ad are the suggestions that you must accompany the pill with the overall plan which is basically just, as I said, a general, simple 1,200-calorie-per-day diet, or something of that sort.

The subcommittee staff learned of a more sophisticated ear form which has been marketed around the country. This was known as the Acu-Form. For this product, each consumer was individually and personally fitted. You put the product on his ear. They would do some sort of fitting to find out where the precise acupressure points are. A couple of ball bearings would be put in the form, so then you wouldn't have to squeeze it. You would be able to put it on and automatically get the acupressure effect. This fitted form was sold from $175 to $300, depending upon how much diet consultation the consumer wished to purchase with the form.

According to the FTC, which investigated this operation, at least 30,000 persons purchased this product, and the consultation did not amount to much more than weekly weigh-ins. The FTC does have the primary jurisdiction in the area of deceptive advertising, and they have provided the subcommittee with a written statement which I would like to place in the record at this time.

Chairman Roth. Without objection. This will be exhibit No. 2.

[See exhibit No. 2 on page 280.]

Mr. Shapiro. I would also like to place in the record materials regarding the Acu-Form product, including selected advertisements.

Chairman Roth. So ordered. This is exhibit No. 3.

[Exhibit No. 3 may be found in the files of the subcommittee.]

Mr. Shapiro. Fraudulent diet products are often marketed through the mails, and I am certain you are all familiar with the types of ads we have here on the right. They can be seen in magazines and periodicals, usually guaranteeing incredible weight loss, usually or often through miracle discoveries and sometimes in extremely short periods of time.

The Postal Inspection Service is the primary Federal agency when the mails are used, and the subcommittee's investigation has indicated the Service currently maintains a very aggressive attitude toward these mail order operators.

The Postal Service has also submitted a written statement for the record, and I would like to have that placed in the record at this time.

Chairman ROTH. Without objection. This will be exhibit No. 4.

[See exhibit No. 4 on page 297.]

Mr. SHAPIRO. Some individuals have told the subcommittee staff that the Postal Inspection Service is often too aggressive and becomes arbitrary in their enforcement actions. Other marketers avoid the Postal Service by selling their diet products in other ways, such as direct sales, and others have now turned to television advertising, asking potential customers to phone in their orders, use their credit cards and then they send the products through UPS and, in this case, the Postal Service is without jurisdiction.

It should be pointed out that the Postal Service cannot curtail the general sales of any particular product. Only the FDA can do that. The Postal Service can only go after particular manufacturers or marketers.

Before moving on to the very low calorie diets, I would like to very briefly discuss products which contain phenylpropanolamine, PPA. These are designed to suppress appetites. Two examples of these products are, again, these pills advertising on the right, PPA pills. You can purchase PPA pills in any store—Dexetrim; Acutrim. These over-the-counter pills are PPA pills. Millions of dollars are spent each year on these pills. Millions more are spent on the PPA pills that are marketed through the mails.

The problem with the mail order pills, such as these, are the advertising claims. One of the largest mail order marketers of these pills is Richard Suarez from Canton, OH, and these ads are from Mr. Suarez's operations. Through a variety of companies, Suarez guarantees weight loss, and one could argue when looking at these ads that the purchaser is receiving a pill which is unavailable elsewhere. But that is not true. These pills are available over the counter; they are the same ones that are sold over the counter. However, Suarez charges much more for them, perhaps twice as much or three times as much, and his often extravagant claims result in much greater disappointment for the customer.

The Postal Inspection Service previously brought a civil suit against Suarez and entered into a consent agreement which did cause him to tone down his ads. Previously, Mr. Suarez's ads did not include the small print diet plan in the lower left corner. The consent agreement with the Postal Service required that that portion of the ad be put in there.

I would like to put the consent agreement into the hearing record, along with some other material related to Suarez's operation which we have received pursuant to a subpoena.

Chairman ROTH. Without objection. We will make this exhibit No. 5.

[Exhibit No. 5 may be found in the files of subcommittee.]

Mr. SHAPIRO. The second basic category of diet products which we reviewed are the very low calorie, or VLC, diets. The concept behind these diets is simple—reduce caloric intake below normal levels, while providing sufficient levels of proteins, vitamins, minerals and other nutrients needed by the body. However, the questions regarding the safety and efficacy of VLC diets are much more complex, and it appears that some of the issues raised cannot be answered because scientists and doctors just do not know enough about how the body works.

The VLC diets were preceded in the 1970's by liquid protein diets where persons were given large doses of proteins in lieu of meals. But reports of adverse reactions, including over 60 deaths, began to mount, and the FDA began an investigation. These reports were enough to persuade most people to stay away from the liquid protein diet, and the FDA, after years of regulatory quagmire and lawsuits issued against them, finally issued a rule in 1984 requiring a warning label for any product which is more than 50 percent protein.

I would like to place a copy of this rule into the record.

Chairman ROTH. Without objection. This becomes exhibit No. 6.

[Exhibit No. 6 may be found in the files of the subcommittee.]

Mr. SHAPIRO. Dr. Pi-Sunyer of the Obesity Research Center at St. Luke's Hospital in New York will appear shortly as a witness and is familiar with the report of liquid protein deaths, and he will be able to discuss the possible causes of these deaths.

The very low calorie diets followed when the liquid diets fell into disfavor. In the VLC diets, the percentage of the protein is decreased and the quality of protein is substantially increased. Other nutrients have also been added. Cambridge Plan International became the first major distributor of VLC products in this country, marketing a 110-calorie shake to be taken three times a day in lieu of all meals. This formula was developed and patented in England by Dr. Alan Howard, a biochemist at Cambridge University. Jack and Eileen Feather, who had marketed other weight reduction products through the mails for years, obtained a U.S. license from Dr. Howard and began to sell the Cambridge plan in 1980.

They began with mail sales and then changed to a direct sales plan with thousands of counselors, independent counselors, who sold the product and provided support to would-be dieters.

Tomorrow, Vaughn Feather, the current president of Cambridge, will appear as a witness.

Cambridge was wildly successful and, as expected, a line of competitor VLC diets appeared. Among these is the Herbalife diet plan, which is one part of an overall nutritional plan featuring herbal products.

The subcommittee's reviews of VLC's focused upon Cambridge and Herbalife largely because these have pervaded the market.

The FDA collects reports of adverse reactions submitted by persons using the Cambridge and Herbalife, as well as all diet plans. The subcommittee's review of FDA's Cambridge files showed that 138 complaints of illnesses had been received, as well as 12 reports of deaths, although it should be pointed out that a significant number of these complaints occurred in 1982 when there was a salmonella problem in one of the Cambridge batches.

For Herbalife, the FDA informed the subcommittee last week that 90 complaints of alleged illnesses had been received, and 32 reports alleging fraud. There also had been four reported deaths of persons using Herbalife, all since last August.

While these numbers may pale in comparison to those persons who experienced no side effects or no adverse reactions, they may, nevertheless, be significant enough to warrant more scrupulous attention by the FDA to determine whether there is, in fact, a cause-

and-effect relationship between the product and the adverse reaction.

As previously mentioned by Chairman Roth, the staff has also reviewed a very, very large number of letters and calls from satisfied users of the Herbalife products, and there are, obviously, many satisfied Cambridge users. Most VLC adverse reaction reports concerns symptoms such as nausea, dizziness, headaches, diarrhea, and constipation. However, some illness reports are much more serious.

The subcommittee staff has contacted a number of individuals who have had more serious adverse reactions while taking Herbalife products. Two individuals, Sue Rohrke and Bernard Lehman, have provided written statements which I would like to place into the hearing record.

Chairman ROTH. Without objection. Exhibit No. 7.

[See exhibit No. 7 on page 303.]

Mr. SHAPIRO. Sue Rohrke's complaint concerns a potassium deficiency problem which caused her to pass out, and we have spoken to at least one other person who has had this same problem using Herbalife products.

Mr. Lehman told us that both he and his wife experienced symptoms mentioned earlier, and he also told us that the Herbalife distributor that sold him his products in Nashville, TN, a few months ago said that the products could help or cause to help cure Mr. Lehman's cancer.

Others who have had adverse reactions have written to the subcommittee and to other media outlets, and we have several letters we would like to place in the record. We have gotten permission to use these letters. Mr. Chairman, I would like to make sure at this time that all medical records and internal FDA records associated with these examples be entered as sealed exhibits.

Chairman ROTH. So ordered. Accepted as Exhibit No. 8.

[Part of exhibit No. 8 may be found in he subcommittee files. Other parts have been retained in the subcommittee's confidential files.]

Mr. SHAPIRO. The subcommittee has also attempted to gather further information on recent reported deaths. Cynthia Lee, whose husband, Bivian, died last November several weeks after beginning the Herbalife diet, has also provided a statement for the subcommittee. We also have an affidavit from Dr. Theodore Van Itallie, head of the Obesity Research Center at St. Lukes-Roosevelt Hospital in New York, and a recognized expert on the treatment of obesity. Dr. Van Itallie has reviewed the medical records from Bivian Lee's death and the death of a New Mexico woman who died earlier this year several months after she started the Herbalife diet. Dr. Pi-Sunyer, an associate of Dr. Van Itallie, has also reviewed these records and will testify concerning them shortly.

Chairman ROTH. We will accept these for the record as Exhibit No. 9.

[See exhibit No. 9 on page 312.]

Mr. SHAPIRO. That will conclude my remarks, and I will be glad to answer any questions that I can at this time.

[At this point in the hearing, Senator Glenn withdrew from the hearing room.]

Chairman ROTH. Are there any questions? If not, we will proceed with the next panel of witnesses.

[Mr. Shapiro's prepared statement follows:]

PREPARED STATEMENT OF HOWARD SHAPIRO

I would like to make some brief introductory remarks on behalf of the subcommittee staff in order to place this investigation in perspective and to explain what is to follow.

The subcommittee's investigation of weight reduction products and plans began in January 1985. The subcommittee is authorized to investigate the efficiency and economy of all branches of the Government. In this case we are concerned with the performance of those Federal agencies authorized to protect the public against fraudulent, deceptive, or dangerous diet products, namely the Food and Drug Administration, the Federal Trade Commission, and the Postal Inspection Service.

The subcommittee also has jurisdiction over all "aspects of crime and lawlessness within the U.S. which have an impact upon or affect the national health, welfare, and safety." Various criminal fraud statutes relate to the manufacture and distribution of diet products and thus create additional authority for this investigation.

The subcommittee staff began this investigation by contacting the three primary Federal agencies involved in this area to gather background information on jurisdiction and authority, and to discuss recent and pending investigations and cases. Agency file reviews were also conducted, reviews which encompassed scientific and medical reports, investigative files, and complaints received from diet product consumers, concerning economic loss as well as adverse physical reactions. These file reviews also enabled the staff to identify the major types of diet products being marketed, and the major manufacturers and marketers in the country.

Numerous contacts were then made with manufacturers, marketers, and consumers. In some instances information was obtained through the issuance of subpoenas. The subcommittee purchased a number of diet products through the mails, and obtained other products from consumers. Scientific and medical experts were also consulted to gather information on the safety and efficacy of various diet products, and to describe how the body reacts to weight loss.

FRAUDULENT PRODUCTS

As mentioned by Senator Roth, our investigation has concentrated on two basic categories of diet products. The first category contains those products which appear to be either worthless or virtually worthless. These include all sorts of pills, creams, wraps, and other devices.

For instance, the subcommittee spent $19.95 to purchase this plastic ear form, known as Acu-Ring, from a company in Dallas. I also received an instruction sheet which I would like to place in the hearing record. Although the sheet does not mention it, I was told over the phone, when I ordered the Acu-Ring, that the device is based upon principles of acupressure, developed by a Chinese doctor. The instructions state that I should wear the Acu-Form on my ear, and squeeze it 10 times in succession before meals or whenever I feel the urge to overeat. Then, I can decide if I can forego the food, and if so, I can set aside the food until I want it.

The sheet also includes a recommended food program, also described as an "essential" part of the diet plan. This recommended program is merely a list of foods from six basic food categories, with some limited menu recommendations.

This is one way to try to avoid enforcement actions based upon alleged deceptive advertising—by devoting a small portion of the instructions or advertising to an explanation of the overall diet "plan." The small print states that the product only works as advertised if an accompanying diet plan is followed. These plans generally consist of meal and menu suggestions for a typical reduced calorie diet, perhaps 1200 calories or so. The reason for this plan is simple; the only way to lose weight is to reduce net caloric intake. Wearing this plastic ear form cannot, by itself, cause weight reduction. Whether it can, in some persons, serve to suppress appetite, is a question to be answered by our expert witnesses. Many diet product marketers deceive the consumer by making the diet "plan" a very small part of their ads and leaving the overall impression that the products do the work.

The subcommittee staff also learned of a more sophisticated ear form which has been marketed around the country. This device, known as the Acu-Form ear mold, was developed by Dr. Francis McCall, currently residing in California. For this product, the consumer's ear is personally fitted and ball bearings are placed into the plastic form at exactly the correct acupressure points. The Acu-Form product was primarily marketed in 1982 and 1983 by an attorney from Texas, Thomas Dardas. Mr. Dardas obtained a license from Dr. McCall and set up more than 40 Acu-Form franchises across the country. The fitted ear form was sold for $175–$300, depending upon how much diet "consultation" the consumer wished to purchase along with the device. According to the Federal Trade Commission, which investigated this operation, at least 30,000 persons purchased the Acu-Form product and plan, and the "consultation" did not amount to much more than weekly weigh-ins. The FTC eventually closed down the Acu-Form operation by entering into a consent agreement with Mr. Dardas.

The FTC has the primary jurisdiction in the area of deceptive advertising, although we have been informed that the FTC often defers action when either the FDA or the Postal Inspection Service are more appropriate agencies for action. One reason for this would be the ability of these latter agencies to take action more expeditiously. The FTC has provided the subcommittee with a written statement which I would like to place into the record and I would like to place materials regarding the Acu-Form product into the record, including selected advertisements.

Fraudulent diet products are often marketed through the mails. I am certain that we are all familiar with the types of ads seen in magazines and periodicals. These ads normally guarantee weight loss, often through miracle or break through discoveries, and sometimes in extremely short periods of time.

The Postal Inspection Service is the primary Federal agency when mail order sales are used, and the subcommittee's investigation has indicated that the Service currently maintains an aggressive stance towards these mail order operators, given the Service's resources. At this time I would like a written statement received from Chief Postal Inspector Clauson to be placed into the record. Some individuals have told the subcommittee that the Service is too aggressive and is often arbitrary in their enforcement actions. This belief is sometimes evidenced by marketers trying to avoid the Service by selling their diet products in other ways, such as direct sales. Others have turned to television advertising, asking potential customers to phone in the orders and use their credit card numbers for payment, and then sending the products through United Parcel Service. In this case the Postal Service is without jurisdiction.

The powers of the Service were increased through the Mail Order Consumer Protection Amendments of 1983. Nevertheless the Service can only curtail or shut down discrete businesses and individuals. The Postal Service cannot curtail general sales of any particular product, as the FDA can.

By not being able to curtail the sales of particular products, the Postal Service can only bring suit against marketers, and cannot curtail the manufacturers who produce diet pills and creams. The subcommittee has learned that in some instances it is the manufacturer who solicits mail order (or others types of) sellers to market their products. If the particular marketer is put out of business, the manufacturer, whose legal liability is much less (since he is not actually making the deceptive claims; he would still be liable for making unsafe products) merely looks for another marketer. Later this morning the subcommittee will receive testimony from Leo Daboub, who has been in the mail order diet business for years.

PPA PRODUCTS

Before moving on to very low calorie diets, I would like to briefly discuss products which contain phenylpropanolamine (PPA) and are designed to suppress appetite. The issue of whether PPA is safe and effective as an appetite suppressant has been an ongoing controversy within the scientific community for years. An advisory review panel chosen by the FDA concluded several years ago that PPA is safe and effective for this purpose, pending additional studies and taken in appropriate doses, and a final FDA rule is currently being promulgated. It should be pointed out that PPA is an ingredient in many other prescription and over the counter preparations, particularly decongestants, and that extensive hearings have been held before the House Subcommittee on Health and Long Term Care. PSI's inquiry into this category has been extremely limited.

While over the counter PPA pills such as Dexetrim and Acutrim account for millions of dollars in sales, millions of dollars more are spent on mail order diet pills which are identical or nearly identical in composition. The problem with the mail order PPA pills concerns the advertising claims made. One of the largest mail order marketers of these pills is Richard Suarez, based in Canton, Ohio. Through a variety of companies, Suarez guarantees weight loss and one could argue that his ads make it seem that the purchaser is receiving a pill which is unavailable elsewhere. But as stated before, most of these pills are the same as those sold over the counter in drug stores and grocery stores. However, Suarez charges much more per pill, perhaps twice as much, and his often extravagant claims can result in much greater disappointment for the consumer.

The Postal Inspection Service has previously brought a civil suit against Suarez and entered into a consent agreement, which has caused Suarez to change his ads, and particularly to include some mention of the diet "plan" which accompanies the actual pills. At this time I would like to enter this agreement into the hearing record, along with other materials related to Suarez' operations, which PSI obtained pursuant to a subpoena. These include product labels and selected advertisements.

VERY LOW CALORIE DIETS

The second basic category of diet products which PSI reviewed are the very low calorie, or VLC, diets. The concept behind these diets is simple, to reduce the caloric intake below normal levels while providing sufficient quantities of proteins, vitamins, minerals, and other nutrients needed by the body. However, the questions regarding the safety and efficacy of VLC diets are much more complex, and it appears that some of the issues raised cannot be answered because scientists and doctors just do not know enough about how the body works.

The VLC diets reviewed by the subcommittee generally prescribe the same regimen: the substitution of a liquid formula, normally made from a powder and mixed with water, milk, or juice, for two or even three meals a day, and up to one regular meal comprising a limited number of calories.

The VLC diets were preceded during the 1970's by liquid protein diets, where persons were given large doses of proteins in lieu of meals. But reports of adverse reactions, including over 60 deaths, began to mount and the FDA began an investigation. The reports were enough to pursuade most people to stay away from this diet, and the FDA, after years of regulatory quagmire and law suits filed against them, finally issued a rule in 1984 requiring a warning label for any product which is more than 50% protein, and I would like to place a copy of this rule into the hearing record. Dr. Pi Sunyer of the Obesity Research Center at St. Luke's Hospital in New York, who will appear as a witness in a few minutes, is familiar with the reported liquid protein deaths and will be able to discuss the possible causes of these deaths.

The very low calorie diets followed when liquid protein diets fell into disfavor. In the VLC diets, the percentage of protein in the product is decreased and the quality of protein is substantially increased. Other nutrients are also added. Cambridge Plan International became the first major distributor of VLC diets in this country, marketing a 110 calorie shake to be taken three times a day, in lieu of all meals. This formula was developed and patented in England by Dr. Alan Howard, a biochemist at Cambridge University. Jack and Eileen Feather, who had marketed other weight reduction products through the mails for years, obtained a U.S. license from Dr. Howard and began to sell the Cambridge Plan. They began with mail sales and then changed to a direct sales plan with thousands of independent "counselors" who sold the product and provided support to would-be dieters. Tomorrow, Vaughn Feather, the current president of Cambridge, will appear as a witness.

Cambridge was wildly successful, and as expected a line of competitor VLC products were introduced. Among these is the Herbalife diet plan, which is one part of an overall nutritional plan featuring herbal products. The Subcommittee's review of VLC diets has focused upon Cambridge and Herbalife, largely because they have pervaded the market.

The FDA has collected reports of adverse reactions submitted by persons using the Cambridge and Herbalife diet products. The subcommittee's review of FDA's Cambridge files, showed that 138 complaints of illnesses had been received as well as 12 reports of deaths. (A significant number of the illness reports for Cambridge were the result of salmonella problem in 1982.) For Herbalife, the FDA informed PSI last week that 90 complaints of alleged illnesses had been received and 32 reports alleging fraud. There have also been 4 reported deaths of persons using Herbalife, all since last November. While these numbers may pale in comparison to those persons who experience no side effects or adverse reactions, they may nevertheless be significant enough to warrant more scrupulous attention by the FDA to better determine whether there is, in fact, a cause and effect relationship. The doctors we have consulted believe these adverse reaction figures are underreported because people do not associate the product with the reaction, they do not know where to file a complaint, or they do not wish to file a complaint because they purchased the products from friends or relatives. As previously mentioned by Chairman Roth, the staff has also reviewed a very large number of letters and calls from satisfied users of the Herbalife products, and there are obviously many satisfied Cambridge users.

Most VLC adverse reaction reports concern symptoms such as nausea, dizziness, headaches, diarrhea, and constipation. However, some illness reports are much more serious. The subcommittee staff has contacted a number of individuals who have had adverse reactions while taking Herbalife products. (Some of these persons are included in the list of FDA complaints.) Two individuals, Sue Rohrke and Bernard Lehman, have provided written statements which I would like to place into the record. Ms. Rohrke's complaint concerns a potassium deficiency problem which caused her to pass out. Mr. Lehman states that both he and his wife experienced the symptoms mentioned earlier, and that their Herbalife distributor told them that the products could help to cure Mr. Lehman's cancer.

Others who have had adverse reactions have written to PSI and to media outlets, and we have several letters to place in the record I would like to have all medical records and FDA reports associated with these examples entered as sealed exhibits.

PSI has also attempted to gather further information on the recent reported deaths. Cynthia Lee, whose husband Bivian died last November several weeks after beginning the Herbalife diet, has provided a statement for the Subcommittee. We also have an affidavit from Dr. Theodore Van Itallie, head of the Obesity Research Center at St. Lukes-Roosevelt Hospital in New York, and a recognized expert on the treatment of obesity. Dr. Van Itallie has reviewed the medical records from Bivian Lee's death and the death of a New Mexico woman who died earlier this year several months after starting the Herbalife diet. Dr. Pi-Sunyer, an associate of Dr. Van Itallie's, has also reviewed these records and will testify concerning them shortly.

Chairman ROTH. I am delighted to introduce a panel of very distinguished scientists. We have with us Dr. Judith Stern, Dr. Pi-Sunyer, and Dr. Tyler. I think if all three would come forward, please. As I indicated earlier, under our rules, all witnesses are sworn in, so I would appreciate if all three of you would stand and raise your right hand.

Do you swear the testimony you will give before this subcommitteee will be the truth, the whole truth, and nothing but the truth, so help you God?

Dr. STERN. I do.

Dr. PI-SUNYER. I do.

Dr. TYLER. I do.

Chairman ROTH. Thank you very much. As I indicated, we appreciate very much your being here. Dr. Stern is a well-known nutritionist, professor of nutrition at the University of California at Davis, a prolific writer and has published a number of articles in a variety of well-respected journals.

Dr. Pi-Sunyer is an associate professor of medicine at the College of Physicians and Surgeons, Columbia University in New York. He is associate director of the department of internal medicine; associate director of obesity research center at St. Lukes-Roosevelt Hospital Center in New York.

Dr. Tyler is the dean of the schools of pharmacy, nursing, and health science at Purdue University. He is also dean and professor of pharmacognosy at Purdue School of Pharmacy and Pharmacal Sciences, perhaps our Nation's outstanding herbal expert.

I would like to take this opportunity to thank each of you for your valuable assistance in this matter. We look forward to your testimony, and we would ask you to start with Dr. Stern.

TESTIMONY OF JUDITH S. STERN, SC.D., UNIVERSITY OF CALIFORNIA, DAVIS, PROFESSOR OF NUTRITION AND DIRECTOR OF THE FOOD INTAKE LABORATORY; F. XAVIER PI-SUNYER, M.D., OBESITY RESEARCH CENTER, ASSOCIATE PROFESSOR OF MEDICINE, COLLEGE OF PHYSICIANS AND SURGEONS, COLUMBIA UNIVERSITY AND ASSOCIATE DIRECTOR OF THE DEPARTMENT OF INTERNAL MEDICINE; AND VARRO E. TYLER, PH.D., DEAN OF THE SCHOOLS OF PHARMACY, NURSING, AND HEALTH SCIENCES, PURDUE UNIVERSITY, AND DEAN AND PROFESSOR OF PHARMACOGNOSY, PURDUE SCHOOL OF PHARMACY AND PHARMACAL SCIENCES

Dr. STERN. I first would like to congratulate, Senator Roth and fellow committee members, for having the courage to begin this investigation of the safety, efficacy, and marketing of a number of products sold for weight control.

I hope this does result in significant legislation to protect the consumer from significant economic and health hazards, and I hope it will result in strengthening certainly the investigative and enforcement wings of our Government that are concerned with this, including the Postal Service, FTC, and FDA.

Before I begin my testimony, I would briefly like to list some of my credentials, because I know tomorrow there will be some witness that will be testifying for some of the companies, particularly Herbalife, that will claim to have credentials in nutrition and weight control, and I want to establish mine clearly for the committee.

As the Senator pointed out, I am Dr. Judith Stern. I am a professor of nutrition and director of the Food Intake Laboratory at the University of California at Davis. I received by bachelor's in food and nutrition from Cornell University and my masters and doctorate from the Harvard University School of Public Health. I am also a registered dietician. I have been doing research in the area of nutrition and weight control for 20 years, and I am considered an expert in this area. I have written approximately 175 research papers and abstracts which are published or in press in reputable scientific journals. I am also secretary for the North American Association for the Study of Obesity; a member of numerous scientific associations, including the American Society of Clinical Nutrition, the American Institute of Nutrition, and the American Dietetics Association. I serve on the editorial boards of three scientific journals, and I was a member of the nine-member committee which reviewed the Dietary Guidelines for Healthy Americans and, finally, I also write a monthly column on nutrition for Vogue magazine, and I also write on nutrition quackery, and I, too, get lots of letters complaining about the problems associated with weight loss products.

I have been asked to give some guidelines for losing weight; to comment about some specific weight reduction products, which I am familiar with, that have limited value or no value at all; and to talk briefly about some of the hazards, the potential nutritional and other health hazards, posed by various diets, including very low calorie diets; and, finally, to give an assessment of Federal agencies with responsibility in this area and to make suggestions for legislative initiatives.

In terms of guidelines for losing weight, a colleague of mine, Theodore Berland, has published valuable guidelines for evaluating diets in Consumer Guide, Rating the Diets. I have modified it somewhat, and I have about eight guidelines that I would briefly like to list because I think it is important to consider these when evaluating any diets or weight reduction products.

First of all, I think we should be aware of claims that the diet or diet product is a "miracle" or based on a "secret" not previously discovered items. There are no magic cures for obesity, and temporary weight loss can occur because more attention is being paid to what is eaten.

Second, the diet should have been tested in overweight people and compared to results from control subjects on other weight reducing regimens. Findings from these studies should have been published in reputable scientific journals. Anecdotal evidence is not sufficient. If testing has not been done, the diet can only be viewed as experimental and, in fact, even potentially dangerous.

Third, the diet should be nutritionally well balanced with a variety of foods, including dairy products and meats, poultry and fish, fruits, vegetables, legumes and whole grains. And it should be a diet free of complications when followed as outlined, and although very low calorie diets do have a place under medical supervision, certainly individuals going on a diet of less than 1,200 calories a day should consider taking a standard vitamin/mineral supplement not greatly exceeding USRDA for those individual nutrients.

Fourth, a moderate calorie deficiency should be part of the diet plan for individuals in the mildly obese category so that weight loss will follow. Moderately and severely obese individuals may require a more drastic caloric restriction and, again, very low calorie diets should only be followed under qualified medical supervision. They should not be sold like Tupperware by unexperienced counselors. They should also avoid diets based on the premise that calories are not important.

Fifth, the person promoting the diet should be knowledgeable in nutrition, well-respected and have appropriate credentials.

Mr. Chairman, fellow committee members, this really is a problem. We don't have any means of nationally or even by State for evaluating people that claim to be nutritionists, and I think we should carefully look at degrees from unaccredited universities and from mail order universities. Physicians are not necessarily qualified to address nutrition issues without specific nutrition training from accredited institutions in, again, nutrition and, again, that is a great concern of mine.

I am at the University of California, Davis, and I do some of my teaching in the medical school, and I hope our students will not perpetuate the myths we will talk about later today.

Sixth, the diet should be flexible and allow for individual preferences. A variety of foods should be incorporated into the diet and fad foods avoided. Optimally, the diet should be easily adapted to family meals and food available in public places.

Seventh, the cost of the diet should be reasonable. I am very concerned about consumers that spend a lot of money on these worthless products and often these are the consumers that can ill afford the expense.

And, finally, rational treatment for weight loss and for maintenance of reduced weight should include increased physical activity.

What I would like to do for the next few minutes is discuss a few of the numerous supplements and diet devices which are being sold as "miracle" cures for obesity, which don't even work in the short term, and my concern is that many of these products to be discussed use legitimate scientific discoveries and then what they do, they overgeneralize and misinterpret the data.

Two examples I would like to use in this prepared testimony are pills made up of amino acids to promote the release of growth hormones. They are sold under the title of "Dream Away." Other pills contain the hormone cholecystokinin. One of the brand names is Anorex CCK. I think you have some of those products that have been gathered by the subcommittee.

In terms of growth hormone releasers, there are a number of products, such as "Dream Away," which may contain one or both of the following amino acids—arginine and ornithine—which supposedly increase the production of growth hormone. This supplement was popularized by the book "Life Extension" written by Durk Pearson and Sandy Shaw, and the authors claim that these amino acids would stimulate the release of growth hormone which would supposedly burn off fat and put on muscle and stimulate weight loss, and it really does sound terrific. But the question is, do arginine and ornithine release growth hormone, and my answer would have to be, Mr. Chairman, yes, but only when injected into a vein and when relatively large amounts are used, and by that I mean it is unlikely that the small amounts present in the tablets taken orally would have a significant effect on the body's ability to release large amounts of growth hormone.

You can, indeed, take a large enough dose orally, but they aren't present in those pills. And in the April 1985 issue of News and Views, which is a monthly newsletter from the American Council on Science and Health, K.A. Meister writes that "it is even less likely that growth hormone releases could have the astounding effects claimed for them."

Basically, people who naturally secrete large amounts of growth hormone are not necessarily thin, and if this disorder occurs in adults, they develop a disease called acromegaly, which is characterized by disfiguring enlargements of the bones of the face, hands, and feet.

Let's look at the next product that I think you also have up at the desk, and that is cholecystokinin, or CCK. Again, the claims for this are almost too true to believe. The latest nonprescription pill for weight loss supposedly contains this hormone cholecystokinin, or CCK, and advertisements for a CCK pill, and these are made for Anorex CCK, include that it's, and I quote,

> The newest, most exciting, nondiet superstrength weight loss compound that has ever been made available to the general public. It's guaranteed to make you lose pound after pound and inch after inch of bulging, hard-to-get-rid-of-figuring-destroying fat, flab and cellulite . . . without dieting.

Now, at a nationwide conference sponsored by the University of California, Davis, held in the Napa Valley, New York Hospital-Cornell Medical Center researcher Gerard Smith, M.D., summarized the many years of research with CCK, and Dr. Smith is extremely well thought of in the scientific community. And what he said was that when hungry rats and mice and rabbits and sheep and monkeys receive an injection and that is important that they receive the injection of CCK, which is a peptide hormone consisting of 33 amino acids linked together, or its active form which consists of eight linked amino acids, these animals eat less, and the larger the dose, the less they eat, and CCK is also effective when injected directly into the brain of hungry animals.

With people, CCK can cause hungry people to decrease their food intake. However, in a study conducted by Dr. Smith and his associates, a slow intravenous infusion of CCK not only decreased the amount of food eaten, but the length of the meal.

You might ask, Senators, given this information, where can I purchase the product, but before you spend almost $40 for a 3-week supply, you should also know that when you eat a peptide, and that is what CCK is, you digest it; your body just thinks it is a protein like any other food, and you digest it and, in fact, when Dr. Smith fed large amounts of CCK to experimental animals, it had no effect on the amount of food eaten, and according to Dr. Smith, there is no scientific evidence to support the claims that diet pills containing CCK are effective in reducing hunger or reducing weight loss.

Dr. Smith also warns, and I am quoting him, "That there is no evidence that repeated doses of CCK are safe for people." And also, I might add, that when the actual amount of CCK was as said in this pill, Anorex CCK, by Nobel Prize Laureate Dr. Yallo of New York, she found the actual amounts of CCK in these pills to be very low. So even if they could possibly work orally, which they don't, the amounts are so low that it really is like a placebo effect.

The other pill I wanted to talk about, because of my personal experience in part with dealing with some of the ingredients, are grapefruit diets and grapefruit pills. I know the Senator from Florida has a special interest in the grapefruit pills because his State, as well as California, produces grapefruits which basically, I think, is a lovely fruit. It is tasty; it is full of nutrition. But grapefruit is a central ingredient in some weight loss diets and the fruit is described as containing enzymes which act in a catalytic manner enhancing fat catabolism, and there are even companies who market diet pills where one of the "active ingredients" is called "grapefruit essence." And while grapefruit, again, is an excellent low-calorie food, there is neither scientific reason to expect, nor data to support the presence of such substances.

Now, one grapefruit diet was called the "Mayo Diet," and the erroneous association with the Minnesota clinic, the Mayo Clinic, certainly lengthened the life of this fad regimen.

In August 1985, I was an expert witness for the U.S. Postal Service in a lawsuit that they initiated against Citrus Industries, manufacturer of the Super Grapefruit Pill. The pill contains glucomannan, and I am quoting from the claims, "the remarkable natural dietary fiber discovery from Japan . . . that expands in your stomach and gives you a full and satisfied feeling all day long." It also contains "a highly potent grapefruit concentrate," and according to the manufacturer, a natural diuretic—damiana—"to eliminate bloat and puffiness."

Chairman ROTH. Could I just interrupt a moment? I do not want to prevent you from giving your full testimony, but if you could summarize because we do have a number of questions that we will want to ask.

Dr. STERN. The grapefruit pill is obviously not effective in weight loss. Let me summarize that particular item.

I am also concerned with the use of vitamin/mineral supplements that supposedly aid in weight control that are thought to effectively control appetite, and they don't. There are no vitamins and minerals that I know of that effectively control appetite.

[At this point in the hearing, Senator Nunn entered the hearing room.]

Dr. STERN. Assuming that the individual is getting adequate amounts. I am also concerned with the use of mechanical and electrical devices that, basically, often compress the tissue and you may lose inches but, basically, that is because water is lost from the tissues.

Again, I would absolutely agree with Mr. Shapiro's testimony that ear clips, ear molds, and acupuncture and pressure don't result in any fat loss, but just the loss of money spent in buying the product.

What I guess I would like to do is finally summarize what I think are the potential nutritional and health hazards that we should look at when looking at products for weight control. I think we should be concerned, as the FDA has defined quackery, with the direct health hazard and those are products which may cause serious adverse effects.

I think we also should be concerned with indirect health hazards, products which of themselves are harmless but which may delay or deny appropriate medical treatment. I think we also should be concerned with major economic frauds that pose no or little direct or indirect hazard, but which fraudulently promote well-being or health benefits, and also what the FDA has called "minor economic cheats," products labeled with unsupported health claims.

Again, I would like to thank you, Mr. Chairman, for allowing me to present some testimony, and I am sure in the questions, more information will come out.

Chairman ROTH. Thank you, Dr. Stern. What we are going to do is have all three members of the panel give their testimony, because I am sure a number of questions will be directed to all three of you.

At this time, I would like to call upon Dr. Pi-Sunyer to give his testimony. Let me say to all the witnesses today, if you can summarize, that would be most helpful. Your full statement will be included as part of the record. Please proceed.

Dr. PI-SUNYER. Thank you, Mr. Roth. I am Dr. Xavier Pi-Sunyer, associate professor of medicine at Columbia University, chief of the Division of Endocrinology and Diabetes at St. Luke's-Roosevelt Hospital Center in New York, and I am also associate director of our NIH-sponsored Obesity Research Center at St. Luke's.

I am here today to testify particularly about weight loss programs which I believe make fraudulent claims and, in a number of ways, can be dangerous to consumers.

[At this point in the hearing, Senator Rudman entered the hearing room.]

Dr. Pi-Sunyer. I would like to begin by describing some of the goals and problems of weight loss. As you are probably aware, the goal for the obese person is to lose as much fat as he or she can without losing protein. The body is made up of a fat-free compartment and fat compartment. The fat-free compartment is made up of protein and water. If an individual loses fat, he also tends to lose a certain amount of protein and a certain amount of water. The goal is to lose as little protein as possible with as much fat as possible.

If an individual is fasting or taking a very low calorie diet, he requires a certain amount of carbohydrates for utilization by the brain, and he or she gets that carbohydrate from protein precursors. The protein is converted by the carbohydrate and used by the central nervous system.

The liquid protein diets were developed in an effort to reduce this protein loss. However, a number of experiments and investigations done on human volunteers has shown this protein loss is not always stemmed by these liquid protein diets and certainly not in the first weeks of treatment. The cause for this is not clear.

In the 1970's, it was suggested that individuals take 300- to 400-calorie diets of such liquid protein preparations per day. As Mr. Shapiro mentioned, there are at least 78 reported deaths and many of these were investigated by the FDA. The cause of death in these people was sudden death. It was considered a cardiac death, and it was due to an intractable arrythmia, the inability—physicians were unable to suppress the abnormal rhythms that occurred in these hearts. As a result, the heart could no longer pump blood and the individual dies.

It has been suggested two possible causes for these arrythmias. One could be an electrolyte imbalance, and the other is protein loss from the heart muscle. As you are aware, as individuals lose weight, they also diurese, particularly if they have low carbohydrate intake. By diurese, that is water loss in the urine. With the loss, you lose a great many minerals—sodium, potassium, also calcium, magnesium, and chloride.

With this protein loss then you get a change in the internal environment of the cells and cause these cells to be more irritated and, therefore, more prone to arrythmias.

Another possible cause of protein loss may be great enough and preferentially affect heart muscles and then the heart muscles atrophy to some extent, and they might be set up for a greater potential for arrythmias.

What does this have to do with the liquid protein diets we have on the markets today? It has been said the old liquid protein diet is inadequate protein and the present liquid protein diets have adequate protein. It is true most on the market now have casein or soy protein, which is a high-quality protein.

However, some of the arrythmias that occurred recently is with recently high-quality protein. Second, I think the problem that occurs with these preparations is what I would call the liquid protein syndrome. That is, these are marketed with suggestions of taking them somewhere around 300 to 420 calories per day and supplementing once with an extra meal. Many of the people take only the supplement and don't take the meal and, therefore, they are not up in the 800 and 1,000 calorie range which may be recommended but not pushed by the suppliers.

Also, it was clear from the original investigation into the 78 deaths when individuals were taking the supplements separate from the actual formula, many of them stopped taking the supplements. It was not just something that didn't taste very well, so one may not get all the supplementary vitamins and minerals that are required for this.

There is another interesting point about the deaths in low-protein diets and that is my colleague Dr. Van Itallie, in going back over some of those deaths, has found a positive correlation to the victim's prediet body mass and their survival on the very low calorie diets. What that means is those individuals that are less fat tend to be more at risk. The fatter you are, the less likely you are to be at risk for cardiac arrythmias and sudden death. The thinner you are, the more likely you are to be. This is a correlation. It doesn't express causality, but one I am personally concerned with and I know others are concerned, people who are very minimally overweight are buying these preparations and using them. These may be people who are 10, 15, 20 percent overweight who should be on 1,000, 1,200 calorie diets.

[At this point in the hearing, Senator Glenn reentered the hearing room.]

Dr. PI-SUNYER. And they are going on crash diets of 300 and 400 calories.

I wish to focus specifically on certain preparations—Herbalife—which is problematical not only because of all I stated above, but also because it added a number of supplements to the formulas which I believe are either dangerous, fraudulent, or both.

Formula 1 of Herbalife is the main component of the diet. While it is suggested by the manufacturer that it be taken as a substitute for two meals a day and a regular meal be taken, instructions only suggest seeing a physician if less than 400 calories are taken, which implies not eating an additional non-Herbalife meal. Thus, it is likely that many consumers will take the Herbalife preparations as their only food.

If they take only three meals of this preparation at the level of two tablespoons per meal, which is recommended for the 180 to 220 pound range, they will be seriously deficient in protein. If they mix it in juice rather than fat-free meals, they will obtain about 39 grams of protein per day and 12 grams of carbohydrate and much lower amounts than recommended daily amounts of calcium, iron, iodine, and magnesium.

In addition, it claims Formula 1 will allow the body to "use unwanted stored fat tissue for its energy production rather than use its precious protein tissue," which is misleading. Certainly, as I mentioned before, protein would be lost, as well as fat.

Herbalife Formula 2 is in tablet form and contains a number of ingredients which have been used in the past in other fraudulent commercial weight loss preparations. These include kelp, cider vinegar, and papaya. In addition, many other herbs are thrown in which also have never been shown to help in weight loss.

In addition, the claim that lecithin helps dissolve hard fat cells in the body is untrue.

I am also concerned this has pyridoxine chloride, B_6, 25 times the recommended daily allowance. It has been suggested that excessive intake of B_6 may be related to the onset of neurological disease and certainly the claim that B_6 will help nervousness and insomnia and irritability is untrue.

Formula 3 of Herbalife contains high doses of vitamin B_6, 50 times the necessary recommended daily allowance. If you add that to the 25, you are talking about 75 times the daily allowance. This makes for an unacceptable high intake of B_6, thiamine, niacin, and vitamin A. In addition, there is a whole series of unnecessary substances that are herbs.

Formula 4 contains unsaturated fatty acids linolenic, oleic, and linoleic. It is said these are required. They are required, but, in fact, if the individual is taking one balanced meal a day as they suggest, this requirement is not necessary.

The individuals market a substance called NRG which is made up of raw guarana which is supposed to be an energizer and help reduce hunger and fatigue and, in fact, contains a significant amount of caffein and is under misleading labeling.

In summary, it is clear that the manufacturers of these products devised a series of preparations which contain a great number of ingredients which are useless and a number of others which may be harmful. There are a whole series of herbs in the preparations which has not been adequately tested and may have side effects. A number of individuals taking these preparations have complained of feeling very ill, particularly with gastrointestinal symptoms, including nausea, cramps, and diarrhea.

I believe the addition of potentially dangerous and noxious substances to a weight loss preparation should not be allowed. In essence, I believe preparations such as Herbalife are really formulated and should be considered medicines, with all the requirements for proof of efficacy which is required of a drug by the FDA.

In summary, for an obese person to lose weight, it is a very difficult activity; it requires a lot of effort, willpower, modification of behavior, and constant vigilance. To dupe consumers into thinking it can be done easily without danger and in crash programs is fraudulent in the extreme. I believe the companies which do this at the monetary and health expense of the public should be regulated. I believe the public needs to be protected from false claims that can empty its pocketbook and destroy its health.

Thank you very much.

[At this point in the hearing, Senator Cohen withdrew from the hearing room.]

Chairman ROTH. Thank you, Doctor. Next we will call on Dr. Tyler. Please proceed.

Dr. TYLER. Thank you, Mr. Chairman. Good morning. My name is Varro E. Tyler. I currently serve as professor of pharmacognosy, as well as dean of the School of Pharmacy and Pharmacal Sciences at Purdue University. Pharmacognosy is the science of drugs derived from natural sources—plants, animals and microorganisms.

As senior author of the only American textbook in this field, I am generally considered an authority on plant drugs and herbal medicines.

It is a pleasure to be able to testify before you today on some of the products currently being sold as herbal remedies. One of the organizations that is now marketing a large number of such products is known as Herbalife International.

[At this point in the hearing, Senator Glenn withdrew from the hearing room.]

Dr. TYLER. I have a special concern about these herbal products, having studied the "Herbalife Official Career Book" that describes them, having had access to what purport to be the formulation sheets for the individual products, as well as having scrutinized the labels of them, as well as much miscellaneous information provided to the public by Herbalife International.

My detailed comments concerning them appear in a lengthy statement that has been submitted to your staff. However, I would like to highlight some of the significant points which I have in that statement.

Chairman ROTH. Your full statement, of course, will be included in the record.

Dr. TYLER. Thank you. Herbalife Slim and Trim Formulas 1, 2, 3, and 4 consist basically of a protein-rich dietary supplement in combinations of herbs, vitamins, and minerals that are claimed to produce weight loss and to produce a loss of appetite in the consumer.

In my opinion, none of the four products contains any ingredients that would cause significant suppression of the appetite or produce a loss of fatty tissue from the body. With respect to the approximately two dozen herbal ingredients in these products—and I shall not enumerate all of them this morning—the only ones present in sufficient amount to produce any conceivable physiological effects are laxatives, namely senna and cascara sagrada. However, these, too, are present in relatively small amounts, and even their activity is questionable..

A product known as Cell-U-Loss is marketed by Herbalife to be used in conjunction with the Slim and Trim Formulas 1 through 4. It is said to attack cellulite, a form of fat that authorities indicate is really not significantly different from other forms of fat; to promote circulation; and to eliminate excess fluids. Cell-U-Loss does contain six different herbal diuretics. However, they are present in such small amounts in comparison to the usual dose needed to affect the diuretic action that it is questionable if even all six of them together would have a significant activity.

I calculate that if the effect of these six herbs were additive, and that is an unproven statement, but if they were, there would still be about one-third the amount required to create diuresis in the normal adult. Even if they did promote the flow of urine, I know no evidence that such action has any reducing effect on fatty tissue.

The cost of using Slim and Trim Formulas 1 through 4, plus Cell-U-Loss is about $1.50 per day. In terms of health benefit, the patient receives nothing for this expenditure.

Another product marketed by this organization is called Herbalife Herbal-Aloe. It is said to help aid digestion and cleanse the system. Since the exact composition of the product is not known to me, and the company's literature on it is confusing, inaccurate and contradictory, I can only assume on the basis of its stated activity, it may contain some of the laxative anthraquinone glycosides found in aloe. If it does not contain these, there is no basis for the statement that it cleanses the system. If it does, I can only say habitual consumption of such products is not recommended.

Additional concern comes from the fact that two herbs, comfrey and chaparral, are added to this Herbalife Herbal-Aloe preparation. Comfrey is an herb that is a known carcinogen in small animals causing malignant tumors in livers of rats when included in their diets. Some samples of comfrey contain as many as eight different pyrrolizidine alkaloids with hepatotoxic, liver toxic, properties. The comfrey used in Herbalife Herbal-Aloe has not been demonstrated, to my knowledge, to be free of pyrrolizidine alkaloids. Since it is my opinion such comfrey-containing product should not be consumed internally, it is not possible for me to recommend Herbal-Aloe for human consumption.

The second herb about which I have a concern that is added to this product is chaparral. Chaparral is a desert plant which contains between 5 and 10 percent of nordihydroguaiaretic acid. Let's call it NDGA. NDGA has been shown to cause cysts and kidney damage in rats when consumed as part of their diet. It was removed from the generally recognized as safe list by the FDA as long ago as 1968.

I believe prudent consumers will wish to avoid internal use of the Herbal-Aloe which contains NDGA in the form of the chaparral additive.

Another product said by the marketer to increase energy and aid mental alertness is NRG. The letters stand for "Nature's Raw Guarana," the seed of a South American plant known to contain about 5 percent caffeine. The recommended daily dose of NGR would amount to an amount of caffeine roughly equivalent to a cup of strong boiled coffee. Unfortunately, the product is not labeled as caffeine-containing, and many Americans cannot tolerate the drug which produces a host of side effects ranging from nervousness and irritability to rapid or even irregular heart beats in sensitive individuals. Caffeine should not be taken by many Americans, especially those with cardiac problems or with a tendency toward them.

Thus, I regard the literature about this product, which does not mention caffeine at all, as deceptive.

A further Herbalife product is known as Schizandra Plus, consisting of tablets from an Asian tree known as *Schizandra chinensis*. It is said by the company to help combat damage leading to premature aging. The herb has been used in Chinese classical medicine as an antiseptic, astringent and tonic, but there is no substantial evidence, scientific or clinical, to demonstrate it has the effects claimed or even that it is safe for consumption in human beings.

The final product which I shall mention today is known as Tong Kuei, a Chinese name. It is said by the Herbalife Co. to help regulate menstrual function and to provide herbal nutrition for the whole body. I consider this reference to nutrition to be particularly improper. The product is not a nutrient. It is a drug and basically a new drug, as far as the United States is concerned. Let me emphasize, both this product, Tong Kuei, and the previous one, Schizandra Plus, are new drug products in the United States. The Food and Drug Administration should definitely require proof of safety and efficacy prior to permitting marketing of either of them.

In summary, aside from some of the possible laxative and diuretic actions and some potential toxicity, as well, the Herbalife products discussed do not produce significant physiological effects in human beings. Any anecdotal evidence of efficacy must be attributed to the placebo effect; that is, that they do what people who spend their money for them think they are going to do. I object to their being marketed for four basic reasons:

One, none has been proven to be effective and some may well be toxic, at least in some persons.

Two, Herbalife literature and particularly word of mouth recommendations build up false hopes in consumers, most of whom are not able to benefit from the placebo effect.

Three, it seems particularly deceptive to me to lead the public to believe that Herbalife products contain a lot of wonderful herbs with marvelous health-giving properties when the amounts present are too small to have any significant therapeutic effects in humans.

And, four, consumers are thus paying good money for products that have no proven value.

One final statement, please. I believe that we have very adequate laws and regulations in the United States to govern this kind of improper activity. The problem, as was so effectively pointed out in the May 1985 issue of Consumer Reports, is that the Food and Drug Administration is not enforcing the laws and regulations that would bring an end to the deceptive practices of these herb sellers.

I respectfully request the U.S. Senate to take whatever action is required to facilitate the enforcement of these laws and regulations by the Food and Drug Administration. Thank you.

Chairman ROTH. Thank you, Dr. Tyler. I appreciate, again, as does the panel, your being here—all three of you—and giving us the benefit of your expertise in this area.

Let me, if I may, just for a moment, be a devil's advocate. I think we all agree that people of this country are diet conscious. There is very real concern about being overweight; that all of us in one way or another tend to try to keep our weight down. What is wrong with a material that is, as you say, harmless, if it enables individuals to lose weight?

We have had a lot of phone calls; we have had a lot of letters from various people throughout the country saying that, and I am not picking out any particular product right now, but that they work. Let me ask you this basic question.

What is wrong with a substance, if it is harmless—and I am making that assumption for the moment—in letting that be marketed if it really does seem to help, maybe for psychological reasons rather than actual beneficial health? What is wrong with that?

Dr. TYLER. Are you asking me, Senator?

Chairman ROTH. Any of your comments.

Dr. TYLER. I think it will work, but only in a small percentage of the individuals. The placebo effect is a very real effect. There is a relation between the central nervous system, immune system and all of those systems in the body that actually cause it to work. But it will be less than 30 percent of the individuals. So for two-thirds, or approximately two-thirds, of the individuals, it will not work. You have heard only from those who say it will.

Chairman ROTH. Yes.

Dr. STERN. Also, Senator, I think we are confusing weight loss with weight maintenance. Most obese people have lost lots of weight over their lifetime, and they lose and gain; lose and gain. It is sort of a rhythm method of birth control.

The real thing we want to emphasize is permanent weight loss. If they are relying on these products to lose weight and, in fact, if a placebo effect occurs, they don't make any permanent changes in their eating patterns, exercise patterns and that, again, will lead to weight gain.

A colleague of mine, Wayne Stuggard, actually evaluated drugs for weight loss that did work in the short run. They compared it to a sound program of behavior changes. What Dr. Stuggard found in the short run, in the first few months, indeed, the people on the pills did lose more weight than those using nutritional guidance and behavior modification, but a year later, those on the pills had regained more weight and ended up heavier than the people using sound programs.

Also, as a scientist, I object to programs that use pseudoscience to perpetuate false claims for their products. It gives the legitimate scientists a bad name.

Dr. PI-SUNYER. Senator, the mistake there is that they work. In fact, they don't work. The growth hormones don't work; CCK doesn't work taken orally. Many of the preparations that are used do not work. So that the claims they will work and will cause weight loss are incorrect.

Now, to lose weight, you have got to reduce calories.

Chairman ROTH. Let me ask, if I may, this question. Let's assume that the substance, whatever it may be, psychologically enables the individual to successfully diet; that you are right, the real reason the person loses weight is because he or she eats less, but the material, the substance, the natural food—whatever it may claim to be—helps them psychologically to weather that storm or to have the willpower to take in less calories; is there anything wrong with that?

Dr. PI-SUNYER. I think it depends—you have to really classify it according to the preparation. If you are talking about something like a growth hormone pill, it is not going to help them at all. If you are talking about a very low calorie diet, then it is going to help them lose weight, because that is what a very low calorie diet does, puts them on 300 to 400 calories. They are totally different products, and I don't think you can lump them together in one question. They have different dangers.

The low calorie diets have dangers because you lose minerals and vitamins as you lose water. You don't have that problem if you are taking CCK. You just are taking a peptide that you digest and doesn't do any good to you and you are spending a lot of money to get it, and somebody has claimed it is going to help you melt away fat, which it doesn't do.

So people are losing money with no efficacy for some of these preparations. From other preparations they are losing weight, but there are dangers attached to losing that weight.

Chairman ROTH. I agree with your point that it depends on the nature of the product. For example, I think this is one device that is supposed to help you lose weight. Should we outlaw that?

Senator NUNN. Looks pretty good.

Chairman ROTH. My colleague says it looks pretty good. [Laughter.]

Dr. STERN. Yes, we should because it's a fraudulent claim, and I think we with special knowledge, with special responsibilities have to protect the consumer who really can't evaluate the claims. I think we do.

Chairman ROTH. Let me ask you about these substances sold with the very low calorie diets. Would you classify them as natural foods or as drugs? I think all of you testified you felt, am I correct, that Food and Drug has adequate authority at this time? Do you base that on the fact that you view these substances that are sold by the various companies with low calorie diets as drugs?

Dr. TYLER. I certainly view the herbal products in that category because of the claims that are made for them by the company. When they say they are going to cure, mitigate or prevent disease, they become a drug. That is what they say in their literature; therefore, they are drugs.

Chairman ROTH. My understanding is that for at least some of these, their advertisements no longer promote them as drugs.

Dr. TYLER. But you yourself, Senator, in your opening statement indicated that obesity was a disease, if I remember correctly.

Chairman ROTH. Was a what?

Dr. TYLER. Was a disease.

Chairman ROTH. I was certainly quoting, I think, a national health institute.

Dr. TYLER. I certainly agree with that; it is a form of disease. It may be a disease of lifestyle, but if you are taking a product for it, it becomes a drug.

Chairman ROTH. You make an interesting point. You say obesity is a disease and anything that purportedly helps overcome that problem for that reason is intended to be a drug.

Dr. TYLER. Certainly if it is of herbal nature and is a plant drug, as I define an herb; yes.

Chairman ROTH. Yes, sir.

Dr. PI-SUNYER. My feeling is, it is not just a natural food. They are adding a lot of minerals and a lot of vitamins. Many of them have much higher levels than the recommended dietary allowance. I mentioned one preparation had 75 times the recommended amount of vitamin B_6 to be taken per day. It has doubled the amount of vitamin A to be taken a day. I think they are formulated. It is not just natural foods and, as such, I think it could come under the jurisdiction of the FDA.

Chairman ROTH. It is my understanding that certain of these products, I believe it is a fair statement to say, that Herbalife says that it is safe for any human being to take. Would you care to comment on that statement?

Dr. PI-SUNYER. Yes. I think it is particularly of concern for pregnant women and for children who might be taking these preparations. I think we have concern—I think it is well established now—women who are overweight and are pregnant should not lose weight during the pregnancy but only after they have delivered the baby or else there could be some problems in terms of the weight of the baby. And, therefore, I think certainly they should not be taking that preparation.

There is a lot of concern about how to treat children who are growing, and there is really very little clarity among pediatricians about the amounts of protein required, but certainly I think all agree that one should be very careful about limiting the amounts of protein in a child in growing periods.

So I think these are two particular groups of human beings who would be particularly at risk from these kinds of preparations.

Dr. STERN. I would add to that, in the Herbalife literature, and this is something—it is called "The Herbalife Nutrition Program for Fun and Easy Weight Control." There is a question-and-answer page, and one question is, "Is it safe for a pregnant woman?" And the answer is, "Normally, except for those who must maintain a strictly controlled diet."

I would agree with Dr. Pi-Sunyer it is not safe for pregnant women and pregnant women should not go on a caloric-restricted diet. They should gain weight at a normal weight for pregnant women.

Additional concern is for lactating women, women who breast feed. They also should not be severely restricting their caloric intake in order to provide appropriate nutrition for the baby, and we know that severe restriction of calories will cut down on the milk supply of the woman.

And I, too, have great reservations about weight loss in children. I have here an issue, the January 1984 issue of the Herbalife Journal, and on the cover, we have a child, before-and-after picture where she is talking about a weight loss of 35 pounds for a 10-year-old. Again, pediatricians are in disagreement about weight loss for children and for children that are not grossly overweight and who might be 10 years old entering into that rapid-growth period, many pediatricians want them not to gain weight but not to lose weight, and so there are strong questions that are raised in the marketing of this product and who they are selling to.

Chairman ROTH. You mentioned, and I will end this line of questioning and defer to my colleagues because I want to try to keep a 10-minute rule, there are constant changes in the medical profession and elsewhere as to what is good for you, what is bad for you. I was delighted to read a few years ago that spinach really isn't good for you. [Laughter.]

When there are such differing theories and concepts, why should the Government try to step in and prevent the marketing of products that at least some people are persuaded is helpful to them? For example, under FDA, I think a few years ago, we made a major exception with respect to vitamins. If I recall correctly, the processes were so slow that people felt we were preventing them from what was rightfully theirs. So we carved out some exceptions.

Don't we run into the danger of doing this for, as you suggest, the regulation of these products, while long-term testing be made of them?

Dr. TYLER. I don't think so. I think health matters are particularly complex and difficult to understand by even people well versed in them. I think the public needs additional protection for health than they do for many other things.

In the case of the vitamins, exceptions were made because the water soluable vitamins, particularly, are not very toxic.

Chairman ROTH. Are not what, sir?

Dr. TYLER. Not very toxic, even in large doses. But in this matter where there is such a large amount of propaganda, advocacy literature made available to the American public saying these things are just great, try them out; it won't hurt anything, but your pocketbook perhaps, I think that there is a responsibility that Government has to step in and regulate these things. You certainly do with all other forms of drugs. Why make an exception for these herbal drugs?

Chairman ROTH. Because part of the argument centers, I guess, on whether or not they are a drug. I understand your position is that these definitely are drugs. Dr. Stern.

Dr. STERN. I would also add that vitamins taken in excess in large doses also act as drugs, and I am concerned that they, too, should be looked at. The problem of taking minerals in excess, there is a problem when you look at these products knowing exactly what is in it, and, for example, we reviewed the Herbalife literature, and we came to the conclusion that if you took all of the products in the recommended dosage, there might be dangerous levels of selenium in the products. It might be as high as 225 micrograms, but it really is very hard to get this from the literature, and I would think in the very least, whether these are food supplements legally or drugs legally, there should be a full nutritional label on these, and I would redefine the nutrition label for these products. I would want everything listed in terms of all the vitamins and minerals for which RDA's have been established and others that recommended ranges have been established. We have no idea what is in a lot of these products.

Chairman ROTH. Dr. Pi-Sunyer?

Dr. PI-SUNYER. I think your suggestion would be well taken if there are no alternatives. There are alternatives. Consumers can go to the grocery store and buy him or herself a 1,000-calorie diet and lose weight. It is not as if you are depriving the public ability to lose weight. They can lose weight without this product. This product doesn't necessarily add anything specific to the market that is any more effective than taking 600 to 1,000 calories in another way without danger.

Chairman ROTH. My 10 minutes are up. I believe, Senator Gore, you are next.

Senator GORE. Thank you, Mr. Chairman. I appreciate it. I have just a few questions. You mentioned the placebo effect. Isn't there something else involved here in addition to the placebo effect that is of a similar character? A placebo is something that works because the individual believes it works, and by some process that we do not fully understand the mind mobilizes, whatever, and the belief of efficacy translates for a certain percentage of patients into a genuine efficacy; is that a fair definition of placebo effect?

But in addition to the placebo effect, you have with diet plans the tendency of some plans to enable the individual to use it as a crutch to focus his or her attention on what the person is eating to use it as kind of a blueprint to aid in mental discipline, whereas without any such crutch, they are just going to pick and chose and eat too much as is normally the case; is not that a legitimate distinction?

Dr. TYLER. I would place it personally under the general category of the placebo effect, just as I would place a bet that two people might make that one could lose more weight than the other. You have a stimulus to do so because of that bet. Therefore, I would say all of these three things we have been talking about are basically placebos.

Senator GORE. Don't feel like you have to speak up here. Let me ask you about ketosis. Let me describe my understanding, and you tell me if I am wrong about it.

When the body is deprived of calories—in other words, when the caloric intake is less than the energy burned, then the body burns up stored fat. If the body burns up more stored fat than is required for energy use, then ketones are produced; is that correct?

Dr. PI-SUNYER. That is correct.

Senator GORE. Some have described ketones as similar in concept to ashes left over from the burning of the stored body fat; is that a useful metaphor or misleading?

Dr. PI-SUNYER. It is only misleading in the sense that the ketones still have a caloric content, whereas the ashes wouldn't. They are broken down into fragments.

Senator GORE. Some have claimed that the ketones themselves have some kind of appetite-suppressant effect. Is there any basis for that?

Dr. STERN. That has been unsubstantiated by reputable investigations. In addition, I would add to your definition of ketosis. You also get ketone bodies formed when you use strict carbohydrates, starches and sugars and the diet doesn't have to be particularly very low in calories.

Senator GORE. There has been some recent research into weight loss and weight gain out of Harvard I believe, about the role of metabolism as opposed to caloric intake, and you correct me if I am wrong, basically the theory is when one begins to lose weight, there is a shifting of gears in the metabolic, the underlying metabolic rate and the body finds a new equilibrium point, and when you begin to go down, you begin to pick up speed because of this shifting of the gears in the underlying metabolic rate. If the caloric intake is also reduced, a high percentage of the weight loss begins to take place because of a shift in metabolic rate.

Dr. **Pi-Sunyer**. Actually, it is the other way around. As you lose weight, your basic metabolic rate goes down so it is harder for you to lose weight. It doesn't speed up the weight loss.

Senator **Gore**. All right.

Dr. **Pi-Sunyer**. The body tries to defend its weight by decreasing the metabolic rate so, in fact, as you diet, you sort of work against yourself in a way. It is harder to lose extra weight.

Dr. **Stern**. Also, the greater the reduction of calories, the greater the reduction of metabolic rate.

Senator **Gore**. Would you all three agree that the current state of medical education for doctors in this country is sadly lacking in instruction in nutrition, diet, and related subjects?

Dr. **Stern**. I would absolutely agree with that statement.

Dr. **Tyler**. It is certainly true for pharmacists.

Dr. **Pi-Sunyer**. Yes; I would agree with that. I think a lot more could be done in the medical schools—train physicians in nutritional therapy.

Senator **Gore**. So when you see examples of medical doctors touting a specific nutrition or diet, you should keep in mind they know almost nothing about it? [Laughter.]

Dr. **Stern**. Often that is the case. Dr. Pi-Sunyer is an exception. He is a medical doctor who knows a lot about nutrition.

Senator **Gore**. Dr. Tyler, there have been some claims made about the therapeutic effects of herbs contained in various Herbalife products. There is an advertisement and, frankly, I will ask the staff whether this is a current advertisement or not; I do not know, but I would like to provide to you, Dr. Tyler, a copy of this advertisement.

It says, "Presenting a special blend of 14 herbs. We call this the miracle worker." It makes certain claims for licorice, for example. It says that licorice helps age spots, arthritis, asthma, emphysema, drug withdrawal, is a sex stimulant, helps menopause, et cetera.

Is there any scientific evidence to back up claims of this sort?

Dr. **Tyler**. There is some evidence that licorice has very interesting physiological effects in extremely large doses, but the amount that is present in the tablets in this formula 2 would be insufficient to produce any of these effects.

Senator **Gore**. How do you know that?

Dr. **Tyler**. From the formulation sheets that were provided to me. I took the amounts, the quantity of licorice in them and it is insignificant.

Senator **Gore**. For something that has been demonstrated to have an effect at a high dose, how do you scientifically determine that a lower dose doesn't have the same effect?

Dr. **Tyler**. Well, there is a threshold of activity for therapeutic action.

Senator **Gore**. How do you know that?

Dr. **Tyler**. By testing in small animals.

Senator **Gore**. Laboratory animals.

Dr. **Tyler**. Yes.

Senator **Gore**. The next one is mandrake, and it says it is helpful with respect to colitis, fever, gallstones, warts, constipation, et cetera. Same question, is there any scientific evidence to back that up?

Dr. TYLER. Mandrake, or hyoscyamine, is a very potent cathartic, and it is my understanding that this has now been taken out of formula 2 and is no longer a component thereof.

Senator GORE. OK. Well, that means this advertisement must be one that is not currently in use in that case.

Dr. STERN. Except, Mr. Gore, it isn't distributed officially by Herbalife. They have replaced it with a new booklet that was published in 1984. But there is a Xerox market and a lot of the distributors, a lot of the people that sell Herbalife products have copies of this and, in fact, I obtained a copy of this from a student who knew a current distributor, and she was using it to substantiate unfounded health claims for the products.

Senator GORE. So the fact that an advertisement is no longer published does not absolve the company from responsibility for its use unless there is some effort to prevent its continued use by the network of distributors that have been given the original material, a recall of some kind or a formal effort to try to get the misinformation off of the market; you would agree with that?

Dr. STERN. I would agree. I would also add to make an active effort to correct the misinformation, to make statements that the licorice in formula No. 2 is not of sufficient quantity to cause any pharmacological effect.

Senator GORE. I have some other questions, Mr. Chairman, but I will submit them for the record to keep within your 10-minute timeframe. I appreciate it.

Chairman ROTH. I think Senator Nunn is next.

Senator NUNN. Following up briefly on Senator Gore's question, if that pill had contained sufficient amount of—what is it—licorice?

Dr. TYLER. Licorice.

Senator NUNN. Would that then be a product that did meet the advertising claims, and the second part of that question, would that be a safe product?

Dr. TYLER. I think you would have to put an awful lot of licorice in the product to get those effects, and I doubt if you are going to compress that amount into a small tablet. But licorice in large doses does produce these effects.

Senator NUNN. Is it something you would recommend for people then if it does all the list of things Senator Gore read out? There ought to be a lot of people interested in it, whatever the size of the pill was. [Laughter.]

Senator GORE. Do you have any particular one in mind? [Laughter.]

Senator NUNN. If I read the list again, there are a couple things I am interested in.

Dr. TYLER. The only thing I recommend licorice for is a pleasant flavoring agent, not as a drug. There are so many better drugs for a condition that you named here that to use licorice for it is absurd.

Senator NUNN. Getting to a rather basic question on this, do you have a definition of overweight? Do any of you have a definition of what is overweight?

Dr. PI-SUNYER. Well, I think one has to differentiate between overweight and obesity, for one thing. Many people are overweight who are not obese. That is part of the problem. Athletes, people who have large muscular builds may be on an ideal weight table overweight, but they are not necessarily obese.

Obese is taken as that percentage of the population that is over about—most people would say about 20 percent above a range of ideal weight that has been calculated by taking either the population as a whole, people less at risk from dying on insurance tables.

Senator NUNN. Who puts out the ideal weight table?

Dr. PI-SUNYER. The one most commonly used is put out by the insurance companies. It is called the Metropolitan Life Insurance Tables. It is calculated on a basis of risk of dying.

Senator NUNN. Do both of you agree with that?

Dr. STERN. The one we are recommending that USDA and Health and Human Services use in the guidelines for Americans is the 1959 Metropolitan Life Insurance Tables because the weights were slightly increased in 1983, and we think that constitutes a risk.

[At this point in the hearing, Senator Gore withdrew from the hearing room.]

Senator NUNN. You didn't agree with that increase?

Dr. STERN. I did in general. Dr. Pi-Sunyer didn't say which Metropolitan Life Insurance Table. I would use the 1959.

Senator NUNN. 1959 would be a lower weight, lower threshold on which to measure, and they raised that, did they not?

Dr. STERN. Yes.

Senator NUNN. What was the reason for raising the weights? Wasn't that a scientific medical reason?

Dr. STERN. They looked at mortality from people insured in their company. They did, in fact, draft things in—smoking, smokers tend to weigh less. So that compounded some of the data.

Dr. PI-SUNYER. I have to submit, we really shouldn't worry about whether we want to use the 1959 or 1984 tables. Either one is fine with me. The people we are talking about are people way above that who are using these products.

Senator NUNN. Twenty percent above would be a definition of overweight or definition of obese?

Dr. PI-SUNYER. Well, I think the NIH Consensus Conference would say obese. They would like to differentiate from overweight people. Most overweight people are people who fall somewhere between 10 percent, maybe 5 percent over the ideal to 15 percent over the ideal. They don't usually go up to 40 percent of the ideal.

Senator NUNN. So obese would be—let's say someone ranged, based on build, so forth, 150 pounds. Anything between 150 and 180 pounds would be overweight, but anything over 180 pounds, which is 20 percent——

Dr. PI-SUNYER [interposing]. No; no. What I am saying is there are some overweight people who don't have excess fat, and they are healthy people. You take one of these 240-pound football players who has a lot of muscle, a lot of bone. He may not be obese, but he is overweight if you look him up in the tables. He doesn't need to lose weight; he doesn't have excess fat. So there are people in our population who, if they look in the table, would be overweight by that table, but they are not really obese and should not be called obese.

Most of the people who are that way know it themselves. You can look at them and tell they are muscular rather than fat.

Senator NUNN. I am just trying to establish a general rule. You just gave an exception. I am trying to define what is the general rule. Does that 20 percent above the table mean obese?

Dr. PI-SUNYER. Yes, I would say. I think most people——

Senator NUNN [interposing]. 150 pounds, 20 percent would be, what, 30 pounds, plus 150; it would be 180. If you are 150 on the table and you weigh above 180, you would be defined as obese in the general sense?

Dr. PI-SUNYER. Correct.

Senator NUNN. Do any of you have any kind of products you believe are both safe and effective that are on the market now for diets? Anything you believe that you would recommend?

Dr. PI-SUNYER. For weight loss?

Senator NUNN. Yes.

Dr. STERN. I wouldn't recommend any products; no.

Senator NUNN. You would not recommend anything on the market?

Dr. STERN. But I would recommend for some people that are grossly overweight, I would say between 40 or more overweight, I think very low calorie diets have a place—diets like the Cambridge diets—but only under medical supervision. I don't think they should be on the marketplace because of the potential side effects. That is an effect of the products, but it is a health hazard, the potential side effects that I am concerned about with that product.

Senator NUNN. Dr. Tyler, do you have anything you would recommend on the market out there today?

Dr. TYLER. Are you speaking both of prescription and over-the-counter?

Senator NUNN. One at a time.

Dr. TYLER. There are some effective anorexic agents, appetite suppressant agents, that are prescription items only. They are effective usually for a brief period of time. Some of those—amphetamine-type preparations—would be qualified. However, as an over-the-counter product, no, there is none. Phenylpropanolamine, perhaps, but even it loses its effectiveness. I personally would not recommend it.

Senator NUNN. Who puts that out?

Dr. TYLER. A number of companies. These products that were discussed this morning are phenylpropanolamine, but it is marketed by a number of companies, and it is an approved drug.

Dr. PI-SUNYER. I would like to stand on what Dr. Stern said about very low calorie diets. Most people who are taking some of these products are people who are under 40 percent obese. The great proportion of Americans who are overweight are not fat to the extent of being over 40 percent of ideal. They are people who shouldn't be on those very low calorie diets.

We can argue whether people who are 60 percent should be for a while on those very low calorie diets, particularly if they have diabetes and hypertension under a doctor's supervision to try to get that weight down, but those individuals who are between 20, 40, 50 percent overweight, I personally feel should not be on the very low calorie diets, special formulations. They can just take a 1,000-calorie, 900-calorie balanced diet from their supermarket.

Senator NUNN. Let me see if I can understand what you are recommending then. Are any of you recommending a change in the present law regarding these drugs, or these diet preparations?

Dr. PI-SUNYER. I don't know enough about the present law. I have to say that first. It would seem to me if they are adding to the preparation a number of vitamins and minerals greater than the recommended dietary allowance, then it is by definition no longer a food, at least by my definition; it's a medicine of some kind, and as such, I would think you wouldn't have to change the law. I would think under the present laws, they can regulate them.

Senator NUNN. Dr. Stern, do you have any recommendation of a change in law?

Dr. STERN. I think, Mr. Nunn, again my understanding of the law isn't perfect, but the House Subcommittee on Health and Long-Term Care in their May 31, 1984, report on quackery recommended a number of changes which I would endorse, and they include increasing the criminal penalties for the promotion of unproven remedies. They include evaluation of unproven remedies, and I would give the Postal Service greater powers in criminal investigation. I think the Postal Service has done an excellent job, but they have to go after every product individually.

The super grapefruit pill is off the market, but Grapefruit Plus, which is essentially the same, is on the market.

Also, I would encourage the FDA and the FTC legally—actually not legally—to make administrative changes to make them react quicker to some of these products. And then in addition to the recommendations of the House subcommittee, I would recommend establishing a national task force to combat quackery through more effective consumer information.

Let me give the FDA—let me clap a little bit for the FDA in one area. They put out an excellent publication called "The FDA Consumer." However, it isn't widely distributed. It should be widely distributed.

I think also there should be an interagency task force to try and combat quackery and fraud. There is an huge duplication of efforts. I think that is a waste of money and it tends to make some of the efforts ineffective.

And, finally, and I don't think one can do this nationally, I think it is really important to encourage States to set a means to evaluate the credentials of so-called health promoters and nutritionists, and in a State where a poodle and a cat can be professional members of the American Association of Nutrition and Dietary Consultants, that's got to be a problem. The consumer doesn't know how to evaluate that.

Senator NUNN. Which State is that?

Dr. STERN. Actually it isn't a State. There is a poodle in New York and a cat in California that are both members. Their owners are bona fide nutritionists and they enrolled their animals, which have human names, human-like names, to make a point that anybody can be labeled a nutrition and dietary consultant, and the public really has no means of evaluating us.

Senator NUNN. Thank you. I think my time has expired.

Chairman Roth. As a matter of fact, the light doesn't work properly. I think we have a special one for the Democrats. [Laughter.] Senator Rudman?

Senator Rudman. Thank you very much, Mr. Chairman. Mr. Chairman, this hearing, so far, has seemed to move on a particular path, and I can understand it, the path of whether or not we have got some use of drugs which are not being properly looked at by FDA. That is certainly a very key issue.

But it seems to me that there is an issue which is far broader and one which, in fact, if there is abuse here ought to be addressed, and that is the whole question of whether the Federal Trade Commission, in its charge from the Congress on deceptive and misleading practices, ought to become more involved with this national scheme.

I have here a very interesting document from the State of California. Of course, I am very familiar, having done it myself for some time with the Consumer Protection Divisions of many of the Attorney General offices—the State of California has brought a lawsuit against Mr. Hughes of Herbalife and his company and Mr. Thompson and several other people. It is a lawsuit. Obviously, it does not mean they are guilty of which they are charged.

They have alleged all of the model FTC laws in the 50 states address—misrepresentation, fraudulent statements, false claims, failure to disclose, illegal marketing plans, which are illegal under most State laws, many FTC laws which generally are quite identical and they are asking for a whole series of injunctions and civil penalties, and so forth.

I want to ask the panel simply this question: I have listened to your expertise and I am very impressed by what you know and how you say it, but beyond that limited area that you are looking at working in the field, do you each feel individually having looked at this problem, is there any question in your mind, or is there a question in your mind, that Herbalife literature, both by the company and the distributors, which I want to talk about in a moment, is deceptive and misleading and fraudulent?

That is a very simple question, and you are the experts. I want to know what you think. Why don't we start with you.

Dr. Pi-Sunyer. Yes; I would think it is.

Dr. Stern. And I would say the claim that it provides good and wholesome, sound nutrition is absolutely false.

Dr. Tyler. Yes; I believe it to be all of those things which you named.

Senator Rudman. The fact of the matter is, the company has disclaimed certain of its original advertising. Senator Gore mentioned some of the advertising, and I have the copies that the State of California has proceeded on. Amongst other things, one of these devices, one of these products cures diabetes or helps—I won't say cures—eczema, indigestion, hypoglycemia. Another treats psoriasis, venereal disease.

[At this point in the hearing, Senator Nunn withdrew from the hearing room.]

Senator Rudman. Another one—cancer, constipation, hayfever, pleurisy. Another one, memory—I would like to get hold of that one. [Laughter.] And there is a whole list of them here.

Curiously, Mr. Chairman, here is a training booklet published well after this material was published by Herbalife and the booklet, which, of course, Herbalife has nothing to do with, has all of the same claims by a distributor. So looking at that, and I know you have seen some of these booklets, do you get some feeling that there is some connection between what Herbalife used to do and no longer does and what their distributors now do and are able to do because there are so many of them?

Dr. STERN. Absolutely. Senator, could I pose a rhetorical question to you?

Senator RUDMAN. Fine.

Dr. STERN. If you were then told that your intestinal villi were clogged, would you become alarmed? And you might take some of these products if you were then told that these would unclog the villi.

First of all, intestinal villi don't get clogged; they renew themselves every couple of days, and if they did get clogged, you wouldn't be able to absorb the nutrients from your food, and you would lose weight actually.

Senator RUDMAN. Well, as a matter of fact, isn't it true for the kinds of things that are alleged in these training booklets and originally in the Herbalife literature and other diet companies, not just Herbalife, but the fact is that people are desperate, whether it is from obesity or whether they, in fact, have cancer, people are desperate and is it not true that people will reach out and grab almost anything and are prime targets for exploitation whether or not they are obese or suffering from some other disease?

Dr. TYLER. That is certainly true. Such people want hope, not facts.

Senator RUDMAN. Mr. Chairman, I am looking forward to the hearing tomorrow; particularly I am looking forward to hearing people from the company and how they want to talk about the link between what they used to say and what they say now.

I also will say to you, Mr. Chairman, these hearings are going to have a very salutary effect because I intend to have the transcripts of these hearings prepared at my own expense and shipped to every attorney general office in the Union, and I am sure this will be a welfare case for people who work for Herbalife. Frankly, I always felt States can take better action than the Federal Government. I do think the Chairman of the FTC ought to look at this also.

I draw no conclusions as to whether there is a basis for a charge here. If it walks like a duck, sounds like a duck and it looks like a duck, it is normally a duck. Thank you.

Chairman ROTH. Thank you, Senator Rudman. There are a few more questions that I would like to continue with.

Dr. Stern, I would address this one question to you with respect to some of these energetic contour creams, ear forms, tinted sunglasses. Do you have any sort of rough figure or numbers of how many people in this country purchase these kind of worthless products?

Dr. STERN. I really don't, Senator Roth. I am sure it is hundreds of thousands and millions of people, but I don't have that figure available. Perhaps staff does.

Chairman **Roth**. Is there such a thing as cellulite? Is this a different kind of fat.

Dr. **Stern**. It is not a different kind of fat. It was a word coined in the early 1900's to describe that dimply type of fat that appears on women's buttocks, hips and thighs, and there is no such thing as a special fat called "cellulite."

Chairman **Roth**. If either of you gentlemen want to comment, please feel free. Is there any product which can eliminate cellulite?

Dr. **Stern**. No, there isn't. A low-calorie diet can help eliminate fat, is the cornerstone of eliminating fat.

[At this point in the hearing, Senator Rudman withdrew from the hearing room.]

[Letter of authority follows:]

U.S. Senate,
Committee on Governmental Affairs,
Senate Permanent Subcommittee on Investigations,
Washington, DC.

Pursuant to Rule 5 of the Rules of Procedure of the Senate Permanent Subcommittee on Investigations of the Committee on Governmental Affairs, permission is hereby granted for the chairman, or any member of the subcommittee as designated by the chairman, to conduct open and/or executive session hearings without a quorum of two members for the administration of oaths and taking testimony in connection with hearings on Weight Reduction Products and Plans. These hearings are to be held on May 14 and 15, 1985.

William V. Roth, Jr.,
Chairman.
Sam Nunn,
Ranking minority member.

Mr. **Rinzel**. Mr. Chairman, if you don't mind, I would like to ask Dr. Stern a question. You mentioned in your testimony in answer to some questions about the lack of standards for nutritionists, people who call themselves nutritionists. Are you familiar with a university by the name of Dansbach University, which I believe is located in California?

Dr. **Stern**. Yes, I am.

Mr. **Rinzel**. Could you tell us what you know about that institution?

Dr. **Stern**. It's a mail-order university and depending on your prior education, you can with anywhere from $3,000 to $5,200 get a doctorate in nutrition. You do have to fill out certain forms and the pastor of your church will administer certain exams, but this self-study program is based on books written by Adelle Davis and Carlton Fredericks that have dubious nutritional value. You do have to write a paper, a dissertation that may take you 3 to 4 weeks and, again, the whole program may take you about 6 months to get a doctorate.

I might add, while I am not particularly slow or fast, it took me 5 years of studying, of taking many courses in Harvard and doing a lot of research to get my degree.

Mr. **Rinzel**. Is this an accredited school?

Dr. **Stern**. It is not an accredited university.

Chairman **Roth**. Let me ask any one of you, if someone goes on a diet and starts consuming a new item and experiences nausea, vomiting, diarrhea or constipation, what would you recommend? Dr. Tyler?

Dr. TYLER. I would recommend they stop immediately.

Dr. PI-SUNYER. I think I would, too. It depends on what they were doing, what they were taking. If they were taking a new substance, I would certainly suggest the initial treatment they stop that particular new substance and go back to regular food or generous levels of caloric intake.

Chairman ROTH. Do you prescribe different kinds of diets depending upon how much overweight a person is?

Dr. PI-SUNYER. Yes. If an individual is, for instance—not just how much overweight they are, but also how active they are. If an individual is taking in 3,000 calories and you cut that individual to 1,000 calories, you made a deficit of his intake of 2,000. If the individual is only taking 1,400 calories and you cut him down to 2,000 calories, he will be taking nothing. So you really have to pattern it on the amount of intake the person was previously taking and the amount of energy expenditure he would have during the day, so it does vary from individual to individual.

You wouldn't put a 100-pound woman—well, you wouldn't put her on any diet. You wouldn't put a 150-pound woman who should be 110 on the same diet as somebody who is 300 pounds.

Chairman ROTH. Dr. Tyler, I have two or three questions I would like to ask you with respect to herbs. Can there be a difference of potency of herbs based on what part of the plant is used?

Dr. TYLER. Very definitely. The capsule of the poppy plant contains morphine; the seeds contain none. It is very dependent on the part of the plant; yes.

Chairman ROTH. Can there be a difference of potency based on the weather conditions in which they are grown?

Dr. TYLER. Yes. Usually weather conditions change the quantity, not the quality of ingredients; the quantity, the amounts. One would have to know precisely. There are assays, for example, for many of the active constituents in plant drugs. These need to be carried out to determine if the products are there and in what amounts.

Chairman ROTH. Finally, do herbs lose their potency over time, and can this happen during the shipping time, for example, from overseas to the United States?

Dr. TYLER. They certainly do. There are some plant drugs that should not be used after they have been stored more than 6 months or 1 year, but it is dependent upon each particular species.

Chairman ROTH. I want to thank each of you for being here today. We may have additional questions, so we will keep the record open for an additional 10 days, and if you would be so helpful as to return your response in writing, I would appreciate that. Thank you very much.

[The prepared statements of Drs. Stern, Pi-Sunyer, and Tyler follow:]

STATEMENT
OF
JUDITH S. STERN, SC.D.
May 14, 1985

My name is Judith S. Stern. I am presently Professor of Nutrition and Director of the Food Intake Laboratory at the University of California at Davis. I received my B.S. in Foods and Nutrition from Cornell University and my masters and doctorate from the Harvard University School of Public Health. I have been doing research in the area of nutrition and weight control for 20 years and I am considered an expert in this area. I have written approximately 175 research papers and abstracts which are published or in press in reputable scientific journals. I am secretary for the North American Association for the Study of Obesity (NAASO), a member of numerous scientific organizations including the American Society of Clinical Nutrition, the American Institute of Nutrition and the American Dietetics Association. I serve on the editorial boards of 3 scientific journals. I was a member of the nine member committee which reviewed the "Dietary Guidelines for Healthy Americans." I also write a monthly column on nutrition for Vogue Magazine and I often write about nutrition quackery.

I have been asked to give some general guidelines for losing weight, to comment about some specific weight reduction products of which I am familiar, that have limited value or no value at all, to comment about potential nutritional and other health hazards posed by various diets including very low calorie diets and finally to give an assessment of federal agencies with responsibility in this area and to make suggestions for legislative initiatives.

GUIDELINES FOR LOSING WEIGHT

T. Berland has published valuable guidelines for evaluating diets in Consumer Guide, Rating the Diets (Signet 1983). With some modifications by C. Russ, R. Atkinson and J. S. Stern (Fad Diets, 1985), these guidelines are:

1. Beware of claims that the diet or diet product is a "miracle" or based on a "secret" not previously discovered. There are no magic cures for obesity. Temporary weight loss can occur because more attention is being paid to what is eaten.
2. The diet should have been tested in overweight people and compared to results from control subjects on other weight-reducing regimens. Findings from these studies should have been published in reputable scientific journals. Anecdotal evidence is not sufficient. If testing has not been done, the diet can only be viewed as experimental.
3. The diets should be nutritionally well-balanced; with a variety of food including dairy products; meats, poultry, and fish; fruits; vegetables; legumes; and, whole grains. It should be a diet free of complications when followed as outlined.
4. A moderate calorie deficiency should be part of the diet plan for individuals in the mildly obese category so that gradual weight loss will ensue. Moderately and severely obese individuals may require a more drastic calorie restriction. Very low calorie diets should only be followed under qualified medical supervision. Avoid diets based on the premise that calories are not important.

5. The person promoting the diet should be knowledgeable in nutrition, well-respected and have appropriate credentials. Physicians are not necessarily qualified to address nutrition issues without specific nutrition training from accredited institutions.
6. The diet should be flexible and allow for individual preferences. A variety of foods should be incorporated into the diet, and fad foods avoided. Optimally, the diet should be easily adapted to family meals and foods available in public places.
7. Cost of the diet should be reasonable.
8. Rational treatment for weight loss and for maintenance of reduced weight should include increased physical activity.

WEIGHT REDUCTION PRODUCTS OF LIMITED OR NO VALUE

The inadequacies of traditional medicine to provide a permanent cure for obesity has given rise to an entire industry of entrepreneurs who claim to be able to relieve the frustations of the overweight. The ironic tragedy is that most diets work--at least initially--when they are followed. However, fad diets are usually quite restrictive in their food choices, may have unpleasant side effects, and most people cannot follow them for any length of time. In addition, when daily calories are restricted below 1200, it becomes difficult to satisfy all other nutrient needs. Despite these drawbacks, the possibility of a quick "effortless" weight loss is often too attractive for some people to pass by. The aim after all is to lose weight, and the various media ads and diet book liner notes promise to do just that. An example of the lure is seen in the initial water-weight loss of the low carbohydrate diets. Is it a blessing in that it might convince an uncommitted dieter to remain on the diet? More likely it confounds the problem by virtually guaranteeing a regain of weight, and with it a renewal of dieting frustration.

When a prospective dieter takes a chance on a fad diet and finds the numbers of the scale decreasing in rapid fashion, it must bring on feelings of comfort and conviction to continue. With the effectiveness of the diet thus verified, the fad gains its most important sales force--word of mouth. But as the physiological and psychological realities of weight loss finally confront the dieter, the dismal long-term odds are once again borne out.

In contrast to fad diets that restrict caloric intake, there are numerous supplements and diet devices which are also being sold as "miracle cures" for obesity which do not even work in the short term.

Many of the products to be discussed use legitimate scientific discoveries and over generalize and misinterpret the data. Two excellent examples are pills made up of amino acids to "promote" the release of growth hormone (Dream Away) or the hormone cholecystokinin (Anorex CCK).

A. Growth Hormore Releasers

There a number of products such as "Dream Away" which contain two amino acids--arginine and ornithine which supposedly increase the production of growth hormone. This supplement was popularized by the book "Life Extension" written by Durk Pearson and Sandy Shaw. The authors claimed these amino acids would stimulate the release of growth hormone which would supposedly burn fat, put on muscle and stimulate weight loss. Do arginine and ornithine release growth hormone? Yes--but only when injected into a vein and when relatively large amounts are used. It is unlikely that the small amounts present in the tablets taken orally would have a significant effect on the body's ability to release large amounts of growth hormone. In the April 1985 issue of News and Views (from the American Council on Science and Health), K.A. Meister writes that "it is even less likely that growth hormone releasers could have the astounding effects claimed for them." People who naturally secrete large amounts of growth hormone are not necessarily thin. If this disorder occurs in adults they develop a disease called acromegaly which is characterized by disfiguring enlargements of the bones of the face, hand and feet.

B.Cholecystokinin (CCK)

The latest nonprescription pill for weight loss supposedly contains the hormone cholecystokinin (CCK). Advertised claims for a CCK pill (Anorex CCK) include that it's "the newest, most exciting, non-diet superstrength weight-loss compound that has ever been made available to the general public." It's guaranteed to make you lose pound after pound and inch after inch of bulging, hard-to-get-rid-of figure-destroying fat, flab, and cellulite...without dieting."

At a nationwide conference last fall sponsored by the University of California at Davis, New York Hospital-Cornell Medical Center researcher Gerard Smith, M.D., summarized the many years of research with CCK: when hungry rats, mice, rabbits, sheep, and monkeys receive an injection of CCK (a peptide hormone consisting of thirty-three amino acids linked together) or its active form (CCK-

8, which consists of eight linked amino acids), they eat less; the larger the dose, the less they eat. CCK is also effective when injected directly into the brain of hungry animals. With people, CCK is reported both to decrease and increase food intake. However, in a study conducted by Dr. Smith and his associates, a slow intravenous infusion of CCk-8 decreased the amount of food eaten and the length of a meal.

Given this information, you might very well ask where you can purchase this product? But before you spend the almost $40 for a three weeks' supply, you should also know that when you eat a peptide, instead of taking it intravenously, you digest it. When Dr. Smith fed very large doses of CCK to experimental animals, it had no effect on the amount of food eaten. According to Smith, there is no scientific evidence to support the claims that diet pills containing CCK are effective in reducing hunger or inducting weight loss. Dr. Smith also warns, "There's no evidence that repeated doses of CCK are safe for people." Also, the actual amount of CCK in these products is quite low.

C. Grapefruit Diets and Grapefruit Pills

Grapefruit is a central ingredient in some weight loss diets. The fruit is described as containing enzymes which can act in a catalytic manner enhancing fat catabolism. There are even companies who market diet pills where one of the "active" ingredients is called "grapefruit essence." While grapefruit is an excellent low calorie food, there is neither scientific reason to expect, nor data to support the presence of such substances. One grapefruit diet was called a "Mayo Diet" and the tacit, albeit erroneous association with the Minnesota clinic lengthened the career of this fad regimen.

I was an expert witness in August 1984 for the U.S. Postal Service in a lawsuit that they initiated against Citrus Industries, manufacturer of the Super Grapefruit Pill. The pill contains glucomannan, "the remarkable natural dietary fiber discovery from Japan...that expands in your stomach and gives you a full and satisfied feeling all day long," "a highly potent grapefruit concentrate," and according to the manufacturer,a natural diuretic--damiana--"to eliminate bloat and puffiness."

To quote from a summary of my testimony: "In 1980, I conducted a double-blind study of glucomannan for weight loss. The test group was instructed to take one gram of glucomannan before eating. The control group was given a placebo, and both groups were placed on a behavior-modification program designed for weight loss. Both groups lost weight but the results showed that the control group had no significantly different statistical ratings in hunger or loss of weight than did the test group who received glucomannan."

For the hearing, I also reviewed the scientific and medical literature on the effect of glucomannan and similar fibers on weight loss. The literature, including the relevant articles submitted by Citrus Industries, supported my conclusion. The same articles have been submitted to this Subcommittee as proof of "effectiveness" of glucomannan in weight loss. In a number of these studies animals taking glucomannan acutally gained more weight than controls.

I also testified that grapefruit concentrate will not cause or materially contribute to weight loss. And, neither damianan nor any of the pills' ingredients, alone or in combination, is a diuretic. In any case, a diuretic does not cause a sustained weight loss the weight loss is replenished by drinking water.

While the case was being appealed, Citrus Industries response increased their advertising of the Super Grapefruit Pills. In November 1984, the postal service obtained an injunction and withheld Citrus Industry's mail. Although an injunciton Citrus Indsutry agreed to withdraw the super grapefruit pill, there are a number of similar pills sold by different manufacturers.

D. Use of Vitamins and Minerals

We sometimes find weight reduction claims being made for vitamins, minerals and other substances which are necessary for normal health. The claims are usually based on the premise that if a little will help, an excess is even better. If a deficiency symptom can be alleviated by supplying the missing nutrient, it does not automatically follow that you can accelerate the metabolic process above its normal rate by simply supplying that nutrient in excess. Most vitamins are precursors of coenzymes, which when combined with an endogenous apoenzyme, form a holoenzyme--the substance which actually participates in the metabolic process. Once the apoenzyme is saturated, additional vitamin intake does result in more of the active substance. The excess is usually excreted in the case of the water soluable vitamins, or can be stored if the vitamin is fat soluable. In either case, the maximum "vitamin" usage has been achieved. When considering such diets it should be remembered that there are dangers in overconsumption of certain nutrients--particularly some of the fat soluable vitamins, and a number of the trace minerals.

In an article published in Family Circle in 1974, Mary A. Crenshaw claimed that the combination of Kelp (150 mg), Lecithin (600 mg), Cider Vinegar (240 mg), and Vitamin B_6 (50 mg) taken as daily adjuncts to a 1000 kcal, low carbohydrate diet, would promote rapid weight loss through their individual "biochemical functions." These four ingredients have reappeared in a number of diet products, including "Fat Off Plus," pills with grapefruit extracts and glucomannan, in a number of Herbalife's products. The first: kelp, or seaweed, is a natural source of iodine--one of the key components in the synthesis of thyroid hormones. Because the thyroid hormone acts as a metabolic stimulant, promoters claim that by taking extra iodine (kelp) one could increase the metabolic rate and burn off extra calories. In Herbalife's Slim and Trim Formula #2 the inclusion of kelp is like "loading a cannon to wage war on obesity." The oddity of such assertions is that with an excessive iodine intake, the serum levels of thyroid hormone does not increase in euthyroid subjects. In fact, iodine administration actually decreases the hormone concentration in subjects who are hyperthyroid. In a small number of people who are sensitive to ingestion of high amounts of iodine, the taking of kelp could be responsible for the development of myxedema, thyrotoxicosis, or goiter.

The function of lecithin in the "All Four Diet," is to "help dissolve fats already in our bodies and render them easier to burn." Lecithin (phosphatidyl choline) is a phospholipid which is endogenously synthesized and serves as a component of nerve tissue. It is also present in bile where it facilitates the solubilization of cholesterol. Aside from its being a source of choline and a possible source of essential fatty acids, lecithin's value in weight reduction has yet to be established and indeed it can be a source of calories. (Approximately 9 calories/gram.)

The third, cider vinegar, is recommended because "... oil and vinegar don't really mix. Maybe vinegar and my fat wouldn't either, and vinegar might just win out. In one product, Herbalife Slim and Trim #2 quotes that "vinegar...is taken...for obesity."

The fourth ingredient, Vitamin B_6 is recommended for its "role" in fat metabolism, so that extra B_6 could hasten the burning of body fat. Since vitamin B_6 functions in amino acid metabolism, not fat metabolism, there is no substance to this claim.

In a controlled experiment to test the claims of the diet, it was found that any weight loss on a diet which included these 4 ingredients as supplements was due to the decreased caloric consumption, and that the "formula" had no effect when compared to the placebo. As with other faddist programs, the appearance of this diet in popular publications implied sanction and fostered acceptance by the public. Following publication of this diet, there began the manufacture and distribution of dietary supplements which contained the four items in the right "dosage," so the public could reap the benefits of this dietary "discovery." Such products are still being marketed today despite the total lack of evidence of their efficacy.

PREPARED STATEMENT OF F. XAVIER PI-SUNYER, M.D.

I am Dr.Xavier Pi-Sunyer, Associate Professor of Medicine at Columbia University and Associate Director of Medicine and Chief of the Division of Endocrinology and Diabetes at St.Luke's-Roosevelt Hospital Center in New York City.

I am here today to testify about weight loss programs which I believe make fraudulent claims and in a number of ways can be dangerous to consumers.

I wish to begin by describing the goals and the problems of weight loss. In an obese individual, the goal is to lose as much fat as possible while retaining as much lean body mass or protein. The human body is made up of a fat and a fat-free compartment. The fat-free compartment is essentially the lean body mass, which is made up of protein and water. The protein makes up all the active working cells of the body and it is this protein component which is responsible for maintaining all the vital life forces. Also, part of this protein component is all the muscle of the body, including the muscle of the heart.

If an individual goes on a total fast, since a certain amount of carbohydrate is necessary to keep the central nervous system alive, and since carbohydrate stores are very quickly depleted, carbohydrate is made from protein precursors. That is, the individual breaks down his/her protein into sugar and loses nitrogen in the urine in the process.

The liquid protein diets were developed in an effort to reduce this protein loss. However, a number of experiments which have been done on human volunteers have shown that protein loss is not always stemmed by these liquid protein diets and many individuals continue to lose protein throughout their period of dieting. The cause for this is not clear to date.

In the 1970's, it was suggested that individuals take 300-400 calories of such preparations per day. As you well know, there were at least 78 reported deaths which the FDA investigated. What were the causes of death? It is unclear, but there are a number of possible causations. The deaths were sudden and they all seem to be cardiac, that is heart, deaths. In the better documented cases which reached the hospital, it became clear that these individuals suffered irreversible heart rhythm problems, which could not be controlled or stopped by any type of suppressive medication.

It has been suggested that these fatal arrythmias are due to electrolyte imbalances. Electrolytes are elements such as sodium, potassium, calcium, magnesium, and chloride which are present in the body as ions and are extraordinarily important in the life of cells, maintaining the internal environment of the cells in a biochemical equilibrium which will allow membrane transport of nutrients, nervous impulses, respiration, etc. to occur.

With very rapid weight loss, and particularly with diets low in carbohydrate, there is an early diuresis, that is, loss of water via the urine. This accounts for much of the weight loss of crash diets and much of this water is reaccumulated when the diet is stopped.

With this water loss, great amounts of sodium, potassium, and chloride are lost, as well as lesser but substantial amounts of calcium, magnesium, and other minerals. These must be replaced. If they are not, the electrical integrity of biological membranes may be lost and one potential outcome of this may be cardiac arrythmias.

Also, the protein loss may be great enough to deplete some tissue stores, and this loss may preferentially affect key tissues. There is convincing animal data that if one tries to rapidly induce weight loss in fat rats, that heart protein will be lost faster than other protein. If so, then a possible cause for the heart problems in dieting individuals could be from a protein depletion of the heart muscle fibers. There is some data from autopsied cases studied by the FDA to suggest that this was true and several articles have appeared in the medical journals describing this.

Now, what has this to do with the liquid protein diets presently on the market? These diets now have higher quality protein and are supplementing vitamins and minerals. The problem with these preparations is what one could call the liquid protein syndrome. This syndrome occurs because an individual wishes to lose weight very rapidly and is persuaded by the advertisements of the diets that they will be effective in this respect. The diets give 300 to 400 calories per day (both Herbalife and the Cambridge Diet do this) and then suggest that more calories be taken with another meal, to make up to at least 800-1000 calories. The individual taking the protein wishes to get on with it, and takes only the preparation. Also, in the Herbalife preparation, because taking the extra supplements may be tedious and not tasty, these may be omitted. Also, even though some preparations, such as the Cambridge diet, suggest that these diets be taken for a limited time only, that is 4 weeks, many users take it for a longer time than this. Other preparations, such as Herbalife, do not give any time limits for their use. They also do this without any monitoring of their blood electrolytes or any medical supervision whatsoever. The net result can be severe side effects, including death.

I wish to emphasize that the marketing of these preparations as absolutely safe diets not requiring medical supervision tends to abet the problem.

There is a further observation of the use of the liquid protein diets or such "crash" diets which I wish to bring to your attention. A reexamination of the data of the victims of the liquid protein diets of 1977 and 1978 by my colleague, Dr.T.B.Van Itallie, has disclosed a positive correlation (r=0.84) between the victims' prediet body mass index and their duration of survival on the very-low calorie diets. In other words, the ability to defer the lethal effects of severe caloric restriction seems to be a function of the proportion of body fat before dieting. That is, the less fat you are the more dangerous these diets are for you, the more likely you are to lose life-requiring protein, and the more at risk of dying you are. Since these preparations are bought without restriction, many people take them who are not very fat, and these people seem to be particularly at risk.

I believe that all persons beginning diets of this kind should be made aware of the possible risks involved. It is particularly important that they limit the time of the diet to 4 weeks at the most and that they be under the care of a physician with frequent monitoring of their heart and their blood chemistries. Careful supplementation of minerals and vitamins is required. Mildly obese individuals should not start on these programs.

I wish now to focus specifically on Herbalife. This preparation is problematical not only because of all I have stated above but also because it has added a number of supplements to the formula which I believe are either dangerous, fraudulent, or both.

Formula 1 of Herbalife is the main component of the diet. While it is suggested by the manufacturer that it be taken as a substitute for 2 meals a day and that a regular meal be taken, the instructions only suggest seeing a physician if less than 400 calories are taken, which implies not eating an additional meal. Thus it is likely that many consumers will take this as their only meals. If they take only three meals of this preparation, and at the level of 2 tablespoons per meal, as recommended in the 180-122 lb. range, they will be seriously deficient in protein if they mix it in juice rather than fat-free milk. If they only take Formula 1, they would obtain only 39 gm of protein per day, 12 grams of carbohydrate (plus that from juice), and much lower than recommended daily amounts of calcium, iron, iodine, and magnesium. In addition, the claim that this Formula 1 will allow the body to "use the unwanted stored fat tissue for its energy production rather than use its precious protein tissue" is misleading. Certainly, as mentioned above, protein will be lost as well as fat.

Herbalife Formula 2 is in tablet form, and 6 are recommended to be taken per day. These contain a number of ingredients that have been used in other fraudulent commercial weight-loss preparations in the past, with no evidence of any effect. These include kelp, cider vinegar, and papaya. In addition, many other substances are thrown in, which also have never been shown to help in weight loss, such as dandelion, fennel, parsley, chickweek, senna leaves, saffron, burdock root. I am most concerned in this preparation with a pyridoxine HCl (vitamin B6) level of 25 times the recommended dietary allowance. There has been recent published data suggesting that excess intake of vitamin B6 may be related to the onset of neurological disease. The claim that excess B6 will help nervousness, insomnia, and irritability is untrue.

The claim that lecithin helps to dissolve hard fat cells in the body is untrue.

In summary, Formula 2 is mostly fraudulent and, with regard to vitamin B6, is dangerous.

Formula 3 of Herbalife is to be taken in three tablets per day. Each three tablets contain a number of substances in much higher concentration than is necessary or safe. Vitamin B6 is taken at 50 times the necessary daily recommended allowance. This is in addition to the B6 taken in Formula 2 at the rate of 25 times the daily allowance. The combination makes for a totally unacceptable high intake of B6. Thiamine (vitamin B1) is taken at 16 times the recommended daily allowance, riboflavin (vitamin B2) at 14 times, and niacin at 7.5 times. Vitamin A is taken at twice the recommended allowance. The B vitamins are water soluble and are excreted in the urine. The three mentioned above do no good at such level and are just excreted in the urine. Vitamin A is more problematical. Constant excess vitamin A intake can lead to headache, blurred vision, nausea, vomiting, loss of hair, and liver enlargement. Thus, these tablets are dangerous and should not be available as they are over the counter.

In addition, a whole series of worthless substances have been added to the tablets. These include kelp, watercress, parsley, syloid, klucel LF, and dulse powder. The claim that Formula #3 will aid in the production of red blood cells is presumably based on the iron content which is actually very low at 3 mg. per day. The claim that it will aid in the production of antibodies is unfounded. The fraudulent claim is also made that it will reduce nervousness.

Formula 4 of Herbalife is recommended to be taken in three capsules per day. This contains 513 mg of the unsaturated fatty acids linolenic, oleic, and linoleic . Although these will not hurt anyone, they are not necessary if one balanced meal is taken each day. Thus, to say that they are required is fraudulent. While it is true that a small amount of fatty acids are nutritionally important and necessary for growth, it is a very small amount, and if the individuals truly take one balanced meal per day, they should get the necessary fatty acids without any trouble, without requiring the supplement.

In addition, the Herbalife marketers suggest that each individual taking the diet should take three tablets of Cell U Loss. This preparation contains 4 times the recommended dietary allowance of Vitamin C, 1.5 times the recommended amount of iron, plus a whole series of worthless powdered extracts, including buchu, couch grass, cornsilk, hydrangea,juniper berry, vva ursi, kelp, and cider vinegar. The claim that this preparation will help get rid of cellulite, which are said to be pockets of "fat, water, and waste fluid" is utterly without foundation. It is a misleading and fraudulent claim.

Herbalife NRG is made up of 800 mg of raw guarana in each tablet. Two to four tablets are recommended per day. This substance is supposed to be an "energizer" and "to help reduce hunger and fatigue". In fact, this contains a significant amount of caffeine under misleading labeling.

Tang Kuei contains angelica sinensis, chammomile pollen, and brewer's yeast. One to three tablets per day are recommended. It is said to be useful in nutritionally aiding regularilty of menstrual functions and providing "herbal nutrition for the whole body". This is without any medical foundation whatsoever.

In summary, it is clear that the manufacturers of Herbalife have devised a series of preparations which contain a great number of ingredients which are useless and a great number of others which are potentially harmful. There are a whole series of herbs in the preparations which have not been adequately tested and may have side effects which we are not clearly aware of at present. A number of individuals taking these preparations have complained of feeling very ill, particularly with gastrointestinal symptoms, including nausea, cramps, and diarrhea. It may well be that some of the herbs contain substances which are irritative to the human intestine.

I believe that the addition of all kinds of potentially dangerous and noxious substances to a weight loss preparation should not be allowed. In essence, preparations such as Herbalife are formulated and should be considered medicines, with all the requirements for proof of efficacy which is required of a drug by the FDA. With the numbers of vitamins and minerals in greater than required doses and all the extra herbs, it seems to me that such a preparation should be considered a medicine and have to undergo all of the scrutiny and controls of a medication.

In summary, for an obese person to lose weight is a very difficult activity. It requires great effort, will-power, modification of behavior, and constant vigilance. To dupe consumers into thinking that it can be done easily without danger and in crash programs is fraudulent in the extreme. I believe that the companies which do this at the monetary and health expense of the public should be controlled and regulated. The public needs to be protected from false claims that can empty its pocket book and destroy its health.

COMMENTS ON THE SAFETY AND EFFICACY OF HERBALIFE PRODUCTS

VARRO E. TYLER, Ph.D.

My name is Varro E. Tyler. I am presently Professor of Pharmacognosy and Dean of the School of Pharmacy and Pharmacal Sciences at Purdue University, positions I have held for 18 years. My undergraduate education in pharmacy was received at the University of Nebraska, and I obtained the Master of Science and Doctor of Philosophy degrees, with majors in pharmacognosy (the science of natural drug products), from the University of Connecticut. I am considered an authority in the field of plant drugs and herbal medicine. For 20 years I have been an author, and am now senior author, of four editions of the textbook Pharmacognosy, which has been during that period the most widely used testbook for pharmacy students in the field of drugs derived from plants, animals, and microorganisms. I am also the author of a popular book The Honest Herbal that gives definitive information regarding the safety and efficacy of more than 100 of the most commonly used herbal remedies. The latter book was written for lay consumption and has been very favorably received and acclaimed by health professionals concerned about the mass of misinformation on herbs placed before the general public in the United States today.

In recent years, there has been a renaissance of interest in herbal medicine, but unfortunately much of the literature devoted to the field has been of an advocacy nature designed to further the sale of products rather than of a critical scientific or clinical nature. Further, many of the products that have been sold have been developed by individuals lacking adequate scientific knowledge and, as a result, are often ineffective, unsafe, or both. In recent months, I have developed a special concern for those products marketed by the organization Herbalife International, and I am pleased to place on record herewith my comments concerning them.

My information concerning the composition and prices of the Herbalife products comes from three principal sources. These include the Herbalife Official Career Book, copyright 1984; various Formulation sheets (received from the Office of the Attorney General in California) purported to list the quantities of the various ingredeints used in manufacturing the Herbalife products (all except one--Schizandra Plus--are from d & f Industries in Orange, California); and the labels of the products themselves. Various other items of literature, including Herbalife Journal, brochures, price lists, and the like, have also been examined by me.

This organization markets a series of products said by them to effect weight loss in the consumer. There is a basic set of four different products designated Slim and Trim Formulas 1, 2, 3, and 4, and these are supplemented by a product known as Cell-U-Loss, which is recommended for use in conjunction with the first four. Herbalife markets other products of an herbal nature including Herbal-Aloe, N.R.G., Schizandra Plus and Tang Kuei. Because these consist of or contain plant drugs, I shall comment on them, as well.

Slim and Trim Formula #1

This product is described in the Herbalife Official Career Book as a balanced protein powder made from natural vegetable soy, casein and whey protein. I do not have access to the exact formulation data on it; however, it appears to be a more or less standard high protein nutritional product, that is, one containing protein in excess of the optimal amount. It is said by the Herbalife organization to effect weight loss by helping to curb the appetite, to cleanse the system, and to burn excess calories in addition to supplying needed daily nutrients.

Although I understand from nutritionists that there have been some health problems associated with high-protein diet products of this sort, the literature available to me does not indicate that any herbal materials have been added to Slimand Trim Formula #1. Consequently, I shall defer detailed comments on it to nutritional experts.

However, I do wish to say that I believe the product to be falsely represented in the company's literature. There is nothing about a protein powder, per se, that will curb the appetite any more than an equivalent amount of protein derived from eating lean meat, nuts, or the like. Further, no protein powder will "cleanse the system" nor facilitate "burning excess calories." It will supply needed daily nutrients, but no more effectively than a low-calorie diet, carefully balanced for carbohydrates, minerals, and vitamins--as well as protein. Such a diet is recommended for weight loss by the professional nutritionists with whom I am acquainted. It also saves the consumer the additional 46¢ per day that is the cost of Herbalife's Slim and Trim Formula #1.

Slim and Trim Formula #2

This is described by the Herbalife Organization as a special blend of 14 herbs plus kelp, lecithin, vitamin B-6, and cider vinegar that is designed to cleanse the digestive system and naturally help curb the appetite. It comes in the form of tablets with the recommended dosage of two tablets to be taken three times daily.

Examination of the herbal constituents in this formula indicate that, of the large number involved, none is actually present in sufficient quantity to product significant physiological effects. Two are contained in amounts that might exert a very weak effect, at least in sensitive individuals. The first of these is senna, a leaf that contains anthraquinone gylcosides that have a laxative or cathartic action. Each tablet contains a miniscule amount so that the recommended daily dose is about 1/20th of the customary dose of the product needed to exert a laxative effect in the average adult.

The second herbal ingredient present in larger amount than others is cascara sagrada, another anthraquinone glycoside-containing laxative. The recommended intake per day is about 1/8 of the usual dose. However, it is necessary to point out that these two laxatives (senna and cascara sagrada) would, because of their similar ingredients, function in a similar fashion, and therefore, their effects can be considered as potentially additive. Further, they are supplemented by small amounts of dandelion root, which has a laxative effect, and kelp, which in its daily recommended consumption would also act as a bulk laxative. These four ingredients--senna, cascara sagrada, dandelion root, and kelp--might thus be present in sufficient quantity to produce some laxative action, at least in sensitive individuals. However, by normal standards, the amounts of herbs present are insufficient to produce any pronounced physiological action.

The remainder of the herbal ingredients--licorice, chickweed, saffron, gotu kola, echinacea, black walnut, hawthorne berry, fennel seed, dandelion root, parsley, papaya, and burdock root--are contained in minute amounts, less than the recommended consumption. They would, therefore, be without significant physiological activity.

The cost for this formula amounts to approximately 21¢ per day. The consumer would pay this amount for a very questionable weak laxative action at best and, in all likelihood, no physiological effect whatsoever. There is certainly absolutely nothing in the product that would cause a los of fatty tissue or a depressant effect upon the appetite.

Slim and Trim Multivitamin and Multimineral Formula #3

This is described by Herbalife as a multivitamin/multimineral formula with vitamin B-6 and zinc. Examination of the formulation data indicates that it is just that--a fairly standard multivitamin/multimineral preparation.

It does contain minute amounts of herbal products such as alfalfa, kelp, dulse, rose hips, watercress, and parsley, but these are present in such small quantities that they would exert no substantial physiological effect.

The cost of consuming this formula is approximately 23¢ per day. If vitamin deficiency is noted, the product would be useful; if not, it would be a total waste of money for the consumer.

Slim and Trim Linseed Oil Formula #4

This is described in the company literature as an essential part of the Herbalife Slim and Trim program because the oil contains essential fatty acids necessary for proper growth, healthy skin, healthy blood, arteries, and nerves. The fatty acids are also said to be important in the metabolism of cholesterol.

While this may be true, the product again contains extremely small quantities of linseed oil. Linseed oil was formerly used in human medicine as a laxative, but we are dealing her with only 1/60th of the usual laxative dose. It would not produce a demonstrable laxative action in normal adults.

The recommended dose of linseed oil does provide some unsaturated fatty acids that have nutritional value. However, it has no particular advantage over taking equivalent amounts of similar vegetable oils--for example, soybean oil.

The cost of consuming this product in recommended dosage is 10¢ per day, but I do not see that it has any particular advantage over the consumption of regular vegetable oils that are ordinarily present in the kitchen of the average home and are used for culinary purposes. The disadvantage is that this fabricated dosage form is more expensive.

Summary of the Slim and Trim Diet Regimen

None of the four products discussed above contains any ingredients that would cause significant suppression of the appetite or produce a loss of fatty tissue in the body. The latter effect can be produced only by of caloric intake or by increasing the amount of exercise in which the individual participates.

With respect to the herbal ingredients in these preparations, the only ones present in sufficient amounts to exert any conceivable physiological effects are laxatives, namely the senna and cascara sagrada, but also the dandelion root and kelp found in Formula #2. However, these effects would be modestly supplemented by the laxative properties of the kelp and dulse, as well as the small amount of parsley found in Formula #3, and the nearly imperceptible laxative action of the small amount of linseed oil in Formula #4. Therefore, the only conceivable physiological effects exerted by the herbal products in all four preparations would be laxative in nature, and this action is questionable in normal individuals because of the low concentrations present of the active ingredients.

While the doses are generally too small to be considered therapeutic or effective, let alone toxic, it is possible that some health hazard may result from long term use of the anthraquinone-glycoside-containing laxatives senna and cascara sagrada. Prolonged usage of even small amounts may eventually result in "laxative habit," a failure to eliminate properly without continued stimulation of the colon by ever-increasing quantities of such drugs.

No permanent weight loss--that is, loss of fatty tissue--nor loss of appetite, except possibly that which might be atributed to digestive upsets caused by the products, could result from consuming them. For all of this--which is really very little in comparison to the extravagant claims of the Herbalife company—the consumer pays about $1.00 per day.

Results of a comparable nature could be achieved with a balanced low-calorie diet and, if necessary, a possible mineral and vitamin supplement, for a fraction of this cost to the consumer.

Cell-U-Loss

This is described in the Herbalife literature as a product to help beat the cellulite bulge. It is said to attack cellulite, promote circulation, and eliminate excess fluids. Further, it is to be used in conjunction with Slim and Trim Formulas 1, 2, 3, and 4. The product is sold in tablet form, and it is recommended that 3 tablets per day be consumed.

Examination of the formulation data indicates that the herbal constituents in Cell-U-Loss are mostly diuretics, present in very small amounts.

In spite of the relatively small amounts of diuretics present, it is possible that they could have an additive effect and produce a slight diuretic action. This is a rather questionable assumption in view of the fact that if they all did function by the same mechanism (an unproven hypothesis), they still would provide only slightly more than one-third of the daily dose of drug required to produce diuresis in the normal adult. Moreover, and even more important, any increased flow of urine would not decrease the amount of fatty tissues present in the body, nor would it in any way depress the appetite of the consumer. I know of no evidence that indicate that even effective doses of diuretics have any reducing action on the fatty tissue commonly designated cellulite in the popular press. Of course, most authorities deny any real distinction between this lumpy form of fat found in the thighs, hips and buttocks of certain women and other fatty tissue. I use the term, therefore, merely in its popular sense.

The cost of consuming this preparation is 43¢ per day, or, if taken in combination with the Slim and Trim Formulas 1 through 4, the cost to the consumer approaches $1.50 per day for absolute minimal effects insofar as weight loss, appetite control, or any other physiologic function is concerned. I therefore consider the statements made by Herbalife in their literature on this product to be false and deceptive.

Herbal-aloe

It is very difficult to determine just how this product is constituted. Since I lack formulation information on it, it is necessary to rely on data supplied in the Herbalife Official Career Book.

The product is described therein as a tonic from the aloe plan noted in the Bible—both in the book of Numbers and the Gospel of St. John. However, authorities tell us that the aloe plant of the Old Testament, that yielded a fragrant wood known as the aloe wood or lignaloes, was an entirely different species from the aloe of the New Testament which is, in fact, closely related to the one used medicinally today. Thus, the company literature on this product is not only inaccurate but contradictory and extremely confusing as well.

The aloe plant used in medicine today is one of the several species of the genus *Aloe*, usually *Aloe barbadensis*, otherwise known as *Aloe vera*. Basically, two different types of products are derived from it:

1. A bitter juice present in the cells of the leaves just underneath the epidermis, or outer layer thereof, and
2. A mucilagenous gel from the cells in the center of the leaves.

These products have quite different physiological properties. The juice is a potent laxative due to its content of anthraquinone glycosides. The gel has moisturizing and emollient properties and is generally applied externally, particularly in folk medicine, to promote wound healing. The agent responsible for such action is unknown, but it is unstable, and its beneficial effect is not present in most commercial preparations that have been stored for a period of time.

Since the Herbalife product is said to aid digestion and cleanse the system, I can only conclude that it contains at least some anthraquinone glycosides and has, basically, a laxative action. No other significant effect could be expected when the product is used internally.

However, three herbs are noted as being added to the product to make it more effective. Although the amounts added are not specified in the product literature, I have deep concerns about two of them.

One of my concerns regards comfrey, an herb that is a known carcinogen, shown to product malignant tumors in the livers of rats when included in their diet. At least some samples of comfrey contain as many as eight different pyrrolizidine alkaloids with hepatotoxic (liver poisonous) properties. The comfrey used in Herbalife Aloe has not been demonstrated, to my knowledge, to be free of pyrrolizidine alkaloids. Since it is my opinion that such comfrey-containing products should not be consumed internally, it is not possible for me to recommend Herbal-Aloe for human consumption.

The second herb about which I have a concern is chaparral. Chaparral, a desert plant, contains about 5-10% of nordihydroguaiaretic acid (NDGA). NDGA has been shown to cause cysts and kidney damage in rats when consumed as part of their diet. It was removed from the GRAS (Generally Recognized As Safe) list and prohibited from use in products regulated by the Food and Drug Administration as long ago as 1968. I therefore cannot recommend the consumption of any product containing chaparral. I believe that prudent consumers will wish to avoid internal use of the Herbal-Aloe to which it has been added.

N.R.G. (Nature's Raw Guarana)

This Herbalife product is claimed by the marketer to increase energy, to aid mental alertness, and to produce a nutritional lift. It is sold in the form of tablets, 2 to 4 of which are to be consumed before breakfast or at mealtime. Each tablet contains a small amount of granular guarana, the seed of a South American plan known to contain approximately 5% caffeine.

Caffeine is a central nervous system stimulant with a recommended medicinal dose of 200 mg. However, sensitivity to the product varies greatly, and it is perhaps relevant that a cup of boiled coffee, that produces a noticeable stimulating effect in many people contains about 100 mg. of caffeine. The recommended dose of N.R.G. is equivalent, more or less, to a cup of strong coffee.

Unfortunately, the product is not identified as caffeine-containing, and many persons cannot tolerate the drug, which has all kinds of effects and side effects. It has been shown to product anxiety, nervousness, irritability, tremulousness, muscle twitching, insomnia, sensory disturbances, hyperventilation (rapid heavy breathing), tachycardia (rapid heartbeat), cardiac arythmias (irregular heartbeat), flushing, increased urination (diuresis), and gastrointestinal disturbances. Caffeine cannot be tolerated by many persons--especially those with cardiac problems or with a tendency toward them.

Since the product is without appreciable nutritional value, and its stimulating effect is due solely to caffeine, I regard the literature concerning it, in which caffeine is not mentioned, as deceptive in character. It is also expensive. If one consumes four tablets per day as recommended, the cost would be 80¢ per day for a product that produces central nervous system stimulation, diuretic action, and many undesirable side effects in sensitive individuals.

Schizandra Plus

This is a product marketed in the form of tablets that are said to help combat damage leading to premature aging; in other words, the product is essentially being sold as a adaptogen--an agent that increases bodily resistence to stress of all sorts, including disease. Another herbal product commonly sold for this purpose, and perhaps better known to lay persons is ginseng. Two tablets of Schizandra Plus contain 180 mg of a concentrate made from the fruit (berries) of a tree native to eastern Asia that is known botanically as Schisandra chinensis. Also present in the formulation are vitamins, selenium, various amino acids, and bee pollen. I do not have the formulation sheets on this product, so my information is taken from the Herbalife Official Career Book.

Schizandra or schisandra is used in Chinese classical medicine as an antiseptic, astringent, and tonic. There are also reports that it produces vasodilation, that is, an expansion of the volume of the blood vessels. More recently, the drug has been studied for its liver protective properties. It is said to be beneficial in protecting the liver against toxic materials--that is, various agents that cause cytotoxicity, such as carbon tetrachloride or galactosamine. A series of lignans known as schizandrins has been isolated from schisandra and tested for this liver-protective action with some success, but results are not yet definitive. At higher doses, the protective action was apparently reversed, at least in some trials. Further scientific and clinical trials are definitely needed before this new drug can be demonstrated to be both safe and effective and before it can be recommended for use in human beings.

It is not possible for me to comment on the dose of this drug because the strength of the concentrate used in formulating it is not known to me. However, comparisons with animal studies suggest that it is probably very low (as is the case with the herbs found in all other Herbalife preparations) in comparison to amounts actually needed to produce a physiological response. Animal experiments have used dosages in the vicinity of 1.66 g per kg in order to demonstrate activity. While it is not possible to extrapolate directly, this would be equivalent to nearly 1/4 pound of berries administered to a 200-pound person. It therefore apepars that an effective dose of the berries (assuming that the herb is actually active--an unproven hypothesis) would be measured at least in grams or tens of grams, rather than in milligrams.

Tang Kuei

This herbal product is said by Herbalife literature to help establish the regularity of menstrual function and to provide "herbal nutrition" for the whole body. I consider this reference to nutrition to be improper; the product is a drug--and a new drug, at that, insofar as the United States is concerned--and it should not be marketed without adequate proof of safety and efficacy.

Also known as dong quai, dang gui, and pinyan, this drug represents the root of a plan known as Angelica polymorpha var. Sinensis. It has been used in Chinese traditional medicine as an emmenagogue--that is, an agent that promotes menstruation--or to relieve dysmennorrhea--that is, painful menstruation. In addition to treating these so-called female ailments, Tang Kuei is also said in company literature to help "the regularity of the menstrual function" and provide "added herbal nutrition for the whole body."

There is no acceptable clinical or scientific evidence by Western standards that the drug has these effects. Herbalife Tang Kuei consists of the product, together with a small additional amount of chamomile. Chamomile is basically an effective antispasmodic and anti-inflammatory plant drug, but not in such small doses (usual medicinal dose, 15 g). Consumers are directed to take 1 to 3 tablets of the Herbalife preparation daily, for a total of 0.6 g per day of the tong kuei root. The principals governing Chinese traditional medicine are quite different frm those of Western medicine; consequently, such components as drug therapy and dosage are not directly comparable. However, examination of a number of Chinese recipes utilizing tong kuei for various conditions indicates that they recommend daily consumption of 3-15 grams of the root. It is therefore obvious that the amount contained in the Herbalife product is between 1/5th and 1/25th of the Chinese recommended dose. Also, authorities in Chinese traditional medicine have noted that the purported benefits of tong kuei are not obtained with low doses, so it is doubtful if the Herbalife product has any significant physiological activity whatsoever. It will cost the consumer 50¢ per day to take this drug that has no proven effect.

Permit me to emphasize that Tang Kuei and Schizandra Plus are basically new drug products in the United States. It is my opinion that the Food and Drug Administration should definitely require proof of efficacy and safety prior to permitting the marketing of either of these products.

Summary and Conclusions

Examination indicates that, in spite of the company's extravagant claims regarding the virtues of Herbalife products, the recommended doses of those containing quantities of herbs (plant drugs) are, in most cases, too small to exert significant physiological effects. Thus the claims made for them as products producing loss of weight and suppressing the appetite, as well as various other claims made in connection with specific products, are, in my opinion, false and deceptive on two counts. In the first place, the herbs do not produce the effects claimed for them, and in the second place, the dosages are too small to produce such effects, even if the products are active as claimed. Yet some people assert that they have been helped by them in various ways, especially in losing weight. How can this be? The answer lies in the so-called placebo effect.

Placebo comes from the Latin "I will please" and refers to a drug which provides relief for the patient through mental processes rather than through any physiological effect on his disorder. The placebo effect is thus a physiological improvement brought about by a psychological mechanism. "Mind over matter" is a simpler way of putting it. A placebo does for you what you think it will do.

Scientific studies have shown that placebos actually work in some people, at least some of the time. They have been found to be effective for the relief of severe post-operative wound pain, cough, drug induced mood changes, angina pain, headache, sea sickness, and the common cold in a few of the patients suffering from these conditions. More interesting is the observation that placebos work even better when the goal of therapy is some change in behavior (drowsiness or alertness), in subjective sensation (pain or discomfort), or in a response controlled by the endocrine glands or by the autonomic nervous system (blood pressure, acid stomach, asthmatic breathing). Since many of the conditions for which herbal treatment is commonly used fall into these categories, it is completely understandable why some people find them to be of value, at least some of the time. However, this placebo effect must not be confused with actual therapeutic benefit derived from drugs. The Herbalife products do not produce the actual therapeutic benefits claimed for them, and I object to them for the following basic reasons:

1. Some of them may well be toxic, at least to some consumers. There is no satisfactory clinical or scientific evidence to show that schisandra or tong kuei, for example, are safe and effective drugs. Marketing them without proof of safety and efficacy is definitely a health hazard. Further, the habitual

consumption of anthraquinone laxative-containing preparations, even in small doses, may well produce some health hazard in the form of development of so-called laxative habit (failure to eliminate normally without the stimulation of the colon produced by such laxatives.)

The unknowing consumption of caffeine, particularly by individuals suffering from cardiac conditions who are unaware that they are consuming it, is definitely hazardous. Herbal additives, such as carcinogenic comfrey and the potentially toxic nordihydroguaiaretic acid, are also considered by me as potential health hazards.

2. Herbalife literature and, particularly, word-of-mouth recommendations for their product build up false hopes in consumers, most of whom are not able to benefit from the placebo effect.

3. It seems to me particularly deceptive to lead the public to believe that Herbalife products contain a lot of wonderful herbs ("a special blend of 14 herbs") with marvelous health-giving properties when the amounts present in the products are too small to have any significant physiological effects in normal persons.

4. Consumers are thus paying good money for products which have no proven value.

For all these reasons, I believe that Herbalife should be made to prove that their products work as claimed and that they are without harm to the consumer. In short, they must be proven safe and effective before being sold to the public. After all, that is what pharmaceutical manufacturers are required to do with the drug products they market. I do not believe that the manufacturers and marketers of herbal medicines should be treated any differently than the manufacturers and marketers of medicines of other kinds.

I believe that we have very adequate laws and regulations in the United States to govern this kind of activity; the problem, as so effectively pointed out in the May 1985 issue of Consumer Reports, is that the Food and Drug Administration is not enforcing the laws and regulations that would bring the deceptive practices of these herb sellers to an end. I respectfully request that the United States Senate take whatever action is required to facilitate the enforcement of these laws and regulations by the Food and Drug Administration.

Chairman Roth. Our next witness will be Dr. Thomas Locke from Silver Spring, MD. Dr. Locke is an internist who devotes part of his practice to the treatment of obese patients.

Doctor, if you would continue standing, we will swear you in. Please raise your right hand.

Do you swear the testimony you will give before this subcommittee will be the truth, the whole truth and nothing but the truth, so help you God?

Dr. Locke. I do.

Chairman Roth. Thank you very much. Please be seated. Dr. Locke, if you could, I would appreciate you trying to summarize your statement, but your full statement will be included in the record.

TESTIMONY OF THOMAS J. LOCKE III, M.D., SILVER SPRING, MD

Dr. Locke. Thank you very much. I submitted last week a prepared statement that has been amended and for a couple of people from the press who received the original document, a subsequent version is available.

I have been cautioned that I should probably anticipate efforts to tarnish my credibility. As mentioned earlier by Senator Roth, I have in the past been affiliated with Cambridge Plan International. So I will, by way of introduction, establish my credibility so as to preempt any potentially tarnishing remarks that may come in testimony tomorrow.

I did my undergraduate work at Princeton University. I subsequently obtained my medical degree at Howard University. I completed my internship there, and I did my residency training at George Washington University. I am a board certified internist, certified by the American Board of Internal Medicine. I have been in private practice since 1981.

I did have a personal experience with use of the Cambridge formula and, thus, began my interest with the use of very low calorie diets. This was in late 1982. After observing the personal benefits, I observed beneficial effects with selected patients and pursued use of formula diets in my practice at that time.

I served in 1983, part of 1983 and part of 1984 as a member of the Counsellor Advisory Board for Cambridge Plan International, which was a volunteer position where I was asked to provide information to the management of Cambridge Plan International about issues relevant to marketing their products from my perspective as a physician and counselor, having used their products.

Currently, I use at least at any given time three different formula diets in my practice. I have extensive experience with the Cambridge formula. I have more extensive experience with other product subsequent to that one, not that different from the original Cambridge formula.

At this time, I have no vested interest whatsoever in the marketing of any product to the public or otherwise. I am contracted by one pharmaceutical company to teach physicians how to use formula diets in their practice, but beyond this, I have no vested interest in the marketing of any formula diet products at this time.

Of the products being examined here today, my most extensive experience is with the Cambridge formula. I have even more extensive experience with similar products marketed only to physicians, and I do believe that there should also be a role for very low calorie diets, and I will elaborate upon it more in the next few moments, but I do feel that marketing of these products should be done by people who are responsible for their actions and accountable to the people who benefit or suffer from use of these products.

I want to stress in anticipation of your questions that my perspective is that of a practicing physician. I do spend some time in my practice teaching medical students, as well as students from the Allied Health Sciences from George Washington University and Howard University, in my practice. Despite these teaching duties, my perspective is that of a practicing physician, and my concerns, therefore, are for the real life public out there and not necessarily people restricted to the research environment.

I mentioned I have used very low calorie diets in my practice, and there are several observations I must share. It is obviously possible to safely use these formulas. However, the overwhelming majority of the people using these formulas do not do so under medical supervision. This results in generally avoidable and usually reversible problems that arise even under medical supervision.

Monitored persons frequently, as well as unmonitored persons, experience minor problems like hair loss, brittle nails, menstrual irregularities, palpitations, common problems which are sometimes not significant and sometimes they can be life threatening. Lightheadedness and unexplained fatigue are very common problems that would require investigation in an appropriate clinical setting.

My concern about these frequent minor problems is that the sequelae of these type problems tend to be much less when the patient is being monitored medically.

We could get into the complications medically as much as you like. I will defer to your questions in that regard. I do want to stress, and this was omitted from my original draft that I submitted to the committee, that the most serious consequence of unmonitored use of very low calorie diets, in my opinion, is the cessation of use of these formulas prior to loss of a substantial amount of weight. This is often the case for people who desperately need to lose weight and were these individuals allowed an opportunity to consult with a physician or some other appropriate professional knowledgeable about these products, this would avail them of an opportunity to prevent some of these minor problems. They could have their regimen modified appropriately to facilitate continued compliance and very often they could be provided reassurance that the symptoms they are experiencing are self-limiting or reversible.

Most importantly, the occasional serious problem or potentially serious problem that would arise would be identified early. And this would prevent serious sequela.

Frequently, concurrent coincidental problems are inappropriately attributed to a formula diet. Proper identification and treatment of these unrelated problems would facilitate continued weight loss and more optimal result from the use of a very low calorie diet.

Lay people cannot possibly be expected to distinguish diet-induced problems from unrelated current illnesses. The negative stigmata of very low calorie diets today, in my opinion, are more attributable to the consequences of lay marketing than problems inherent to the formulas themselves.

These avoidable problems, the misinformation that the public is overwhelmed with and a lack of guidance and support while using the very low calorie diet have a net effect, I think, of depriving the obese individual of maximal benefit from a potentially very useful therapeutic modality.

I appreciate the comments made earlier by Dr. Stern and I fully agree with her that frequently doctors often lack adequate knowledge about nutrition, per se. However, medical doctors are usually quite familiar with and are capable of recognizing the consequences of malnutrition, and, moreover, they are far more capable of recognizing the side effects of use of very low calorie diets. However little you may think doctors know about nutrition, I think the physicians in general know a lot more about nutrition than the lay people marketing very low calorie diets. These people know a lot less, and I would, frankly, rather subject the health of the general public to the mercy of physicians who are accountable for their actions and liable for consequences of their action more so than to subject the health of the public to the mercy of less informed lay entrepreneurs who are only interested in selfish financial gains.

These obese individuals frequently fall prey to these lay entrepreneurs simply because of their existing emotional problems. These emotional problems may be predisposing factors that resulted in their obesity; they may be a consequence of the obesity. But these emotional problems make them vulnerable when preyed upon by these aggressive entrepreneurs. They, therefore, frequently experience severe psychological trauma as a result of the disappointment due to unrealistic expectations that are fostered by these lay entrepreneurs.

We have heard already how frequently the lay entrepreneurs misrepresent the potential results of using formula diets. I feel that these patients should have their weight-loss effort conducted in a milieu where the likelihood of their long-term success is greater. You can belabor that point to the extent you wish later.

Persons using very low calorie diets under medically supervised structured programs that address increasing their activity, behavior modification, et cetera, use these formula diets for much longer periods of time than persons obtaining products from lay entrepreneurs. I can share data from my practice. I will be happy to make available to you and you can even use data provided by Cambridge Plan International with regards to the use of their formula, data accumulated by Opinion Research Corp. in Princeton, NJ.

They express the use of their formula in terms of duration in weeks. In my practice, people who do well need to use these formulas in terms of months and even years under supervision, and in the medical milieu, the likelihood of adequate longevity of use is far greater than when a product is obtained from a lay entrepreneur.

Dr. Tyler pointed out that the product is used to treat a disease. Obesity is clearly a disease. I think the NIH Consensus has established that fact to the satisfaction of most of the medical community. The fact that this disease should be subjected to treatment with a product means that this product must be then construed as a drug and, therefore, this drug or drugs should be subjected to the same scrutiny as any other drug used to treat any other disease.

Another group of all too frequent occurrences in my experience is the precipitation of adverse effects of prescribed therapy. Individuals who have weight problems frequently have other medical problems for which they make prescribed or even unprescribed drugs. Some drugs will have their effectiveness increased by use of a formula diet, thus enhancing the likelihood of side effects of the drugs. The examples most commonly discussed are those drugs used for high blood pressure or diabetes.

I have experienced unnecessary problems such as blackouts or syncopal or presyncopal episodes by people on the very low calorie diets without medical supervision. Problems such as elevated uric acid in the bloodstream, low blood potassium or high blood potassium, and especially dropping of one's blood pressure when they stand up is a very common observance in patients using these products without adequate medical supervision, especially when they are not receiving adequate instruction in proper use of the formula diet.

Hypoglycemia, especially in diabetics being treated for their blood sugar, is very frequent and the person who is not being adequately monitored is potentially at risk of life-threatening consequences of this development.

Another complication then—and I am going to wrap up quickly—preexisting disease is common among people using very low calorie diets. These illnesses are often precipitated by the use of the formula, per se. In my experience, things like peptic ulcer disease, lactose intolerance, psychiatric disturbances—not frequently discussed in the literature—are actually precipitated during the stress imposed by a very low calorie diet. Problems like gout, diverticulosis, and diverticulitis, dermatologic problems are commonly precipitated—the word "commonly" perhaps is an overstatement—at least occasionally precipitated by the stress of a diet even if it is not related to inherent features of the diet, per se.

For these reasons, I would urge that measures be imposed to mandate that medical supervision be imperative in people using these formulas. To make these formulas available by prescription only, in my opinion, would not be unreasonable.

I do think the distributors of these products should be held liable for dispensing in a manner analogous to a pharmacist who dispenses prescription medications. The relative paucity of serious consequences of use of very low calorie diets, in view of the popularity of these diets, is fortunate. Perhaps this is testimony to their inherent safety. However, unless precautionary measures are imposed, more frequent and serious problems will no doubt occur.

I would like to express at this point that the most serious consequence of lay marketing of these formulas is cessation of use prior to adequate weight loss, thus, depriving a severely obese individual of a potentially very useful therapeutic modality.

The literature with regards to efficacy of very low calorie diets is enormous. I can comment on that, if you wish. I have had extensive experience and will be willing to share with you.

I would like to defer to your questions in order to make sure I discuss anything you want to know about and not just what I think you ought to know.

Let me summarize simply by saying that the use of very low calorie diets, such as the Cambridge formula and others, clearly is a viable option in the management of the seriously obese patient. However, the risks of significant complications from their proper use under medical supervision are considerably less than the complications from persistent obesity. Therefore, they should be maintained as a viable option as treatment for the severely obese patient. The improper use of these formulas results in unnecessary complications and especially premature cessation of use. This limits the value of these formulas in properly selected patients that would benefit from weight loss. The emotionally vulnerable obese individual should be spared the psychological trauma related to repeated failures due to improperly managed weight loss efforts under the auspices of these lay entrepreneurs.

The risks of use of these formulas can be minimized, I think, by mandating medical supervision.

Chairman ROTH. Thank you, Dr. Locke. One question I would like to ask you, and I know Dr. Pi-Sunyer and Dr. Stern are still here, and I would be interested if they had any comments, too. You raised in your testimony that there seems not to be a great proliferation of lawsuits in this area and in a way, that seems, if these various diets are not valid, unusual because I think everybody would agree, we have become a very litigious Nation. Why is it there are so few lawsuits in this area?

Dr. LOCKE. I think that the victims that would potentially gain from these lawsuits, as you would expect would occur, are frequently timid individuals that hide behind a cloak of obesity and, therefore, their shyness keeps them from coming forth and making a claim.

I have seen numerous examples of legitimate damages that should have been followed by a lawsuit, one would think, but I think personalities of individuals affected, their embarrassment to admit they were using products that are controversial and various other factors frequently related to lack of knowledge or unawareness of their rights, et cetera, these type factors are the reasons for the low lawsuits. Plus you have to realize the entrepreneurs marketing these products are very shrewd individuals that have at least covered the bases in regards to their legal protection. Frequently, the individual from whom the victim obtains the product is a friend, relative, neighbor that one would not want to readily bring a lawsuit against.

They function as independent contractors. The people who should be sued are protected by legal technicalities.

Chairman ROTH. Dr. Pi-Sunyer, Dr. Stern, would either one of you care to comment?

Dr. PI-SUNYER. Well, I would just say that charges would be hard to prove. I think that is one of the problems. I think these are sudden deaths. They often occur at home, if they occur. It could be a number of items. These are people, as the doctor mentioned, who are often sick with other conditions, and I think it is difficult to establish causation.

I would also say that I would agree, it is relatively safe—a lot of people who have been on this—relatively safe, but not totally safe. What we are talking about is those few individuals who would get into trouble with this, particularly without medical supervision.

Dr. STERN. Also, I would just add to the statements and say if the side effects are not extremely life threatening, individuals usually don't sue because they become nauseated or dizzy or may have diarrhea and constipation, nonetheless, some of these side effects have to be considered.

Chairman ROTH. Thank you, Dr. Stern.

Dr. Locke, you did serve on the Cambridge Advisory Board. Let me ask two or three questions. What was its purpose? Did it meet regularly? What kind of advice did you give? Did they follow your advice?

Dr. LOCKE. In retrospect, to be honest with you, I am not sure what the purpose of that board was. In my interpretation at the time, I felt I was selected from among over a quarter of a million distributors of their products because of my experience with use of the product in unique circumstances and because of my potential contributions to the board as a physician. I was led to believe they were interested in what I had to say about my observation medically with this formula diet.

I learned, however, that basically our role was to agree with whatever management had to say and pass the word on because we had great influence among the distributors in the communities where we worked. I feel that much of the advice that I offered was ignored. I feel that there was very little interest in the minority of the people who did experience adverse consequences of use of the formula diets.

As a physician, I am forced to be concerned about the exceptions to the rule because that is my job, to find them. The company had a perspective such that they were only interested in the majority of the people that did OK and was most interested in marketing their product. Particularly at that time the company was, and I guess still is, functioning under the auspices of chapter 11 bankruptcy petition and the only interest was on product sales and there were frequent uncomfortable circumstances for me as a physician when the emphasis on sales, per se, overshadowed pertinent things being experienced both medically and nonmedically by distributors of the products and certainly the persons using the products for weight loss.

Chairman ROTH. Let me ask you this: How many patients have you treated using the Cambridge diet plan, and how many of these patients suffered side effects?

Dr. LOCKE. I would say that depending on your definition of a side effect, most people do experience some change in their overall symptomology or well-being when they use a very low calorie diet. But the majority of symptoms experienced are very mild and minor and often remediable.

In terms of number of people treated, I have used the formula you mentioned, the Cambridge formula, probably in excess of 200 to 300 patients for a varying length of time. I have used other formula diets in much larger numbers of patients subsequent to my cessation of using the Cambridge formula.

Fortunately, there are formulas available to physicians now that are not marketed through the lay mechanisms. So you don't have to resort to using products distributed in controversial fashions to allow patients to avail themselves.

Chairman ROTH. Why isn't the proposal that low-calorie diets should be administered by physicians, why shouldn't that be characterized as just a big grab for the doctors?

Dr. LOCKE. That is a good question, and I welcome the opportunity to respond to it. Let me just say quite frankly, as an internist, I am trained to treat most all the consequences of obesity, and I make my living treating problems such as heart disease, diabetes, arthritis, gallbladder problems, all the consequences of obesity. I would make a far greater economic business of my practice focusing on treating the consequences of obesity. For example, in my personal experience, I could probably earn in about a week caring for a diabetic who had a heart attack, for example, in a hospital setting about the same amount of money as I could earn managing a 6-month effort to lose weight using my fees and my program.

So cost effectively, time spent managing obesity, unless you do it in huge volume, is not really a good way for economic gains.

I do feel a moral obligation to maintain an interest in managing obesity simply because a majority of people who come to me with medical problems, more than five out of eight, are obese by definition and most of the problems I see in my practice as an internist are either aggravated by or direct consequences of obesity.

The amount of income gained from selling the product is negligible compared to professional fees and seeing a patient in an office. Economics really should not play a role in a physician's decision to incorporate very low calorie diets into his practice. I view the very low calorie diet much as I would any other drug I would prescribe as a useful therapeutic modality for properly selected individuals and not as a source for economic gains.

Chairman ROTH. Time is moving on. I will ask you one more question. We may want to submit further questions for the record. Is it not true that you have wanted to conduct further tests with Cambridge, and what were the nature of these tests? Did you receive any grants to make such studies?

Dr. LOCKE. I never received any grants. I had been promised a very small grant, almost insignificant in quantity to amplify the experiences such as I have described in my prepared statement. My interest was to see if, indeed, the small number of people that I had experienced who had complications were representative of the public at large. I wanted to amplify that experience, and I did, indeed, request a grant. It was promised by the president of the company, Vaughn Feather, who at the advice of persons unknown to me later decided he would not provide me with that grant. His motives, I guess, would be another issue.

The amount of funds requested and the nature of the grant was something, in retrospect, was quite inconsequential.

Chairman ROTH. Thank you very much, Doctor. Thank you for being here. As I say, we may submit further questions.

Dr. LOCKE. Thank you for having me.

[Dr. Locke's prepared statement and supplemental statement follow:]

Testimony by:

Thomas J. Locke, III, M.D.
Silver Spring, Maryland

TO: U.S. Senate Permanent Subcommittee on Investigations

Re: The Cambridge and other Very Low Calorie Diets

Date: May 14, 1985

(THE FOLLOWING IS A SLIGHTLY REVISED MORE COMPLETE VERSION OF TESTIMONY RENDERED TO THE SUBCOMMITTE ON MAY 14, 1985)

Extensive use of Very Low Calorie Diets (VLCD's), including the Cambridge Diet- tm in my practice has resulted in several observations that I must share. Though it is possible to use these type formulas safely, the overwhelming majority of persons using these formulas do not do so under medical supervision. Frequent generally avoidable problems do arise, even under medical supervision. Monitored patients, as well as persons referred after long periods of unsupervised use may manifest hair loss, brittle nails, menstrual irregularities etc. Palpitations, lightheadedness and unexplained fatigue (generally manifestations of hypovolemia) are occasional complaints. The sequelae of these type problems are much less under medical supervision.

THE MOST SERIOUS CONSEQUENCE OF UNMONITORED USE OF THESE PRODUCTS IS CESSATION OF USE BEFORE SUBSTANTIAL WEIGHT LOSS IS ACCOMPLISHED. OFTEN, PEOPLE WHO DESPERATELY NEED WEIGHT LOSS, DISCONTINUE THE DIET BECAUSE OF MINOR PROBLEMS THAT ARISE. CONSULTATION WITH A PHYSICIAN, OR OTHER APPROPRIATE PROFFESSIONAL, WOULD PROVIDE AN OPPORTUNITY FOR PREVENTION OF MINOR PROBLEMS, MODIFICATION OF THE REGIMEN TO FACILITATE CONTINUED COMPLIANCE, OR REASSURANCE THAT THE SYMPTOMS BEING EXPERIENCED ARE SELF LIMITING OR REVERSIBLE. THE OCCASIONAL POTENTIALLY SERIOUS PROBLEM WOULD BE IDENTIFIED EARLY PREVENTING SERIOUS SEQUELAE. FREQUENTLY, CONCURRENT, COINCIDENTAL, PROBLEMS ARE INAPPROPRIATELY ATTRIBUTED TO THE FORMULA DIET. PROPER IDENTIFICATION AND TREATMENT OF UNRELATED PROBLEMS WOULD FACILITATE CONTINUED WEIGHT LOSS AND MORE OPTIMAL RESULTS. LAY PEOPLE CAN NOT BE EXPECTED TO DISTINGUISH DIET INDUCED PROBLEMS FROM UNRELATED CONCURRENT ILLNESSES. THE NEGATIVE STIGMATA OF VLCD'S TODAY ARE MORE ATTRIBUTABLE TO CONSEQUENCES OF LAY MARKETING, THAN PROBLEMS INHERENT TO THE FORMULAS THEMSELVES. AVOIDABLE PROBLEMS, MISINFORMATION, AND A LACK OF GUIDANCE AND SUPPORT WHILE USING VLCD'S, HAVE A NET EFFECT OF DEPRIVING THE OBESE INDIVIDUAL OF MAXIMAL BENEFIT FROM A POTENTIALLY USEFUL THERAPUTIC MODALITY.

Obese individuals frequently have emotional problems either as predisposing factors to or as a consequence of their obesity. These emotional problems make them vulnerable when preyed upon by aggressive entreprenuers. They therefore frequently experience severe psychological trauma as a result of dissappointment due to unrealistic expectations fostered by lay entrepreneurs who misrepresent the potential results of using formula diets. These patients should have their weight loss effort conducted in a millieu where the likelihood of success is greater. Persons using VLCD's under medically supervised, structured, programs, do so for much longer periods of time than persons obtaining product from lay entrepreneurs.

Another group of all too frequent occurrences is precipitation of adverse effects of prescribed therapy. Augmentation of the efficacy of beta blockers, diuretics, oral hypoglycemics and insulin are particularly common. Persons using blood pressure medications such as beta blockers have presented with severe bradycardia (slow heart rate), syncopal (passing out) or pre-syncopal episodes and wheezing. Aggravation of diuretic (fluid pills) related hyperuricemia (high uric acid), hypokalemia (low potassium) and hyperkalemia (high potassium), as well as orthostatic hypotension (low blood pressure upon standing) have been observed. Hypoglycemia (low blood sugar) in treated diabetics inadequately monitored is not infrequent.

Pre-existing unrecognized problems commonly first become manifest or are aggravated during the use of a VLCD. Using any caloric-restricted diet can be a stressful event. I have observed patients while experiencing this stress develop acute exascerbations of peptic ulcer disease, lactose (milk sugar) intolerance, psychiatric disturbances, gout, diverticulosis and diverticulitis, dermatologic problems (eg. eczema, psoriasis), asthma as well as other less common problems.

Because of these type problems, I would urge that measures to ensure that responsible marketing practices be imposed with use of these type formulas. Medical supervision should be imperative. To make these formulas available by prescription only would not be unreasonable. The distributors of these products should be held liable for dispensing in a manner analogous to pharmacist dispensing prescription medication. The relative paucity of serious complications, in view of the popularity of these type products is fortunate. Eventually, unless precautionary measures are imposed, serious problems will occur. Preventative measures should be implemented promptly to minimize needless suffering.

Medical observations with use of the Cambridge diet are well documented.(1) Much of my experience (2) parallels that of Kreitzman, et.al. (1) with properly supervised patients. Consistent satisfactory weight loss, even sometimes with noncompliant patients, occurs. Improvement in blood pressure in patients with hypertension is impressive. Normalization of blood glucose in type 2 diabetics, disproportionate to the degree of weight loss, is a rather consistent observation in my practice. R. R. Henry et. al. at the University of Colorado (personal communication — unpublished data) have explained this by demonstrating a reduction in hepatic gluconeogenesis (synthesis of blood sugar by the liver) in persons using this formula.

Certain differences in my observations, from those of Kreitzman et.al. (2) merit emphasis: Measurably reduced serum iron levels occurs in more than 30-40% of monitored patients (T.J.Locke.- unpublished data). This observation as Kreitzman et.al. point out is most impressive in menstruating women. However, it occurs in men as well. Frank anemia does not usually develop in my experience. However, significant iron deficiency anemia has been frequently precipitated in patients with predisposing factors e.g. peptic ulcer disease, menorrhagia (heavy menstrual periods) and in one male patient with osteomyelitis (deep seated infection of bone).

Evaluation of palpitations in previously unsupervised and in supervised patients via 24 hour heart monitoring has revealed clinically significant findings. Episodic sinus tachycardia (fast heart rate) as well as paroxysmal supraventricular tachycardia (very fast heart rate) are the most frequent findings in my experience . These particular abnormal heart conditions have been generally easily remediable by volume repletion (increased fluid inake). Though I have not seen electrolyte (eg. potassium) imbalance as a cause for arrhythmias, Lindner reports low serum potassium as a cause of ectopy and ECG changes in a patient using a formula diet not very different from the Cambridge formula. (3)

Extensive data are available to substantiate long term use of VLCD's.(4) Kreitzman et. al. (1) report virtual 100% compliance with the reccomendation not to use the Cambridge Diet as one's sole source of nutrition for more than 4 weeks. I have seen rare patients having used this formula medically unsupervised as their sole source of nutrition for a many as 11 weeks without significant sequelae. I have data from weekly monitored use for continuous periods up to 7 weeks without significant adverse sequelae. Persons using VLCD's like the Cambridge diet should realize that the reccomendation to use the formula for no more than 4 weeks is based on a consent decree- between the U.S. Postal Service, the F.D.A. and Cambridge Plan International- and not as a result of medical or scientific observations. Safe use far beyond 4 weeks has been accomplished. Conversely, complications have occurred prior to 4 weeks. Therefore, continuous medical supervision should always be conducted to recognize and treat problems that occur when using these formulas.

SUMMARY

THE USE OF VLCD'S LIKE THE CAMBRIDGE DIET-TM CLEARLY IS A VIABLE OPTION IN THE MANAGEMENT OF THE SERIOUSLY OBESE PATIENT. THE RISKS OF SIGNIFICANT COMPLICATIONS FROM THEIR PROPER USE UNDER MEDICAL SUPERVISION ARE CONSIDERABLY LESS THAN THE RISKS OF COMPLICATIONS FROM PERSISTENT OBESITY. THEREFORE, THEIR USE AS VIABLE OPTION FOR THE SEVERELY OBESE SHOULD BE MAINTAINED. IMPROPER USE, WITH RESULTANT UNNECESSARY COMPLICATIONS AND PREMATURE CESSATION OF USE, WOULD LIMIT THE USE OF THESE FORMULAS IN PROPERLY SELECTED PATIENTS THAT WOULD CLEARLY BENEFIT FROM WEIGHT LOSS. EMOTIONALLY VULNERABLE OBESE INDIVIDUALS SHOULD BE SPARED THE PSYCHOLOGICAL TRAUMA RELATED TO REPEATED FAILURES DUE TO IMPROPERLY MANAGED WEIGHT LOSS EFFORTS UNDER THE AUSPICES OF LAY ENTREPENEURS. RISKS OF THE USE OF THESE FORMULAS CAN BE MINIMIZED BY MANDATING MEDICAL SUPERVISION.

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SUPPLEMENTAL COMMENTS TO TESTIMONY BY:

Thomas J. Locke, III, M.D.

Silver Spring, Maryland

TO: U.S. Senate Permanent Subcommittee on Investigations

Re: Very Low Calorie Diets

Below are responses to concerns raised during the testimonies not addressed in the originally prepared statement, submitted for the Congressional record.

Re: COMPETANCY OF PHYSICIANS TO DEAL WITH NUTRITIONAL ISSUES

While I agree that the general body of nutritional knowledge among the medical community at large warrants enhancement, the nutritional needs of our obese patients should not be left to the mercy of generally less knowledgeable, self ordained, non-medical nutritional practitioners. This need for enrichment of familiarity with nutritional concepts is widely recognized. The standard medical literature is becoming increasingly more replete with nutritional information to which the medical community is exposed. Continuing medical education (CME) courses on nutrition are widely available throughout the country. Most states maintain very strict requirements of physicians who must participate in a minimum amount of CME courses each year in order to maintain licensure. Furthermore, the majority of practicing physicians have access to consultation with appropriately trained and certified nutritionists who possess knowlege that they themselves and their patients can avail themselves of. Collaboration of physicians and nutritionists in the use of VLCD's must be encouraged. Lay entrepreneurs do not have this access to knowledge and information needed to properly use VLCD's. Neither are they as accountable to their customers as physicians are to their patients.

The most vital role of the physician is to identify and treat pre-existing and intercurrent problems that might alter the reccommended approach to weight loss. The complex physiologic events that take place during any weight loss effort require monitoring of much more than just pounds. The human individual is much too complex and unique to assume that the response of one individual to a weight loss effort will be the same as the next. Side effects of VLCD's, precipitation of latent problems, and aggravation of pre-existing problems, occurs too frequently to allow untrained individuals, incapable of recognizing these events to distribute these products.

Re: VLCD'S AS A TREATMENT OF OBESITY, AND OBESITY AS A DISEASE

Non-medical management of weight loss traditionally approaches the treatment of obesity as a cosmetic issue. It is finally well accepted that obesity (defined as being 20% or more above ideal body weight) is a disease. The NIH consensus earlier this year substantiates this claim. The medical community, our legislative and regulatory bodies and the public at large must readily accept this fact. "Treatment" of this "disease" therefore should only be entrusted to skilled practitioners knowledgeable about etiology, physiologic implications, indications for and complications of specific therapeutic modalities. These treatment modalities must therefore be subjected to the same scrutiny as drugs and other treatment modalities used in the treatment of other diseases.

Given that obesity is recognized as a legitimate medical problem, changes in attitudes about coverage for expenses incurred during medical management of weight loss efforts is needed. It would be more cost effective than deferred expenses due to complications of obesity. In this era of trends toward practicing preventative medicine, it is logical that emphasis should be placed more on medical management of obesity per se, rather than the traditional narrow-minded focusing on its consequences. This need for re-direction of emphasis is equally important for governmental, legislative and regulatory agencies, the insurance industry, and the general public as it is for the medical community. The medical commuity must be challenged by the legislative and regulatory bodies to accept that re-direction of emphasis toward prevention, via treatment of obesity, is a priority of greatest importance. This promises to be a difficult task since treatment of complications of obesity is far more lucrative for the practicing physician, than management of obesity per se. Full endorsement by the medical community of responsible management of obesity would provide better alternatives to persons who now in desperation are forced to turn to entrepreneurs who do not have much concern for their health.

Comprehensive management of weight reduction must include attention to behavioral and lifestyle changes, increased physical activities as well as addressing the dynamics of nutritional, metabolic and physiologic adjustments. These objectives are far more likely to be accomplished under the compassionate auspices of one's physician, particularly when in collaboration with other health care proffessionals eg. nutritionists, rather than at the mercy of non-medical entrepreneurs.

RE: "THE NEW" CAMBRIDGE PLAN

The new official promotional policies of Cambridge Plan International (CPI) are far more acceptable than their original plan of unmonitored use of a 330 calorie per day formula. It remains though that lay people, (many or even most of whom are familiar with the old regimen), are marketing a very low calorie formula , even if the program calls for 800 calories. While I applaud the response of Cambridge Plan International to pressure from the nutritional and medical communities, no constraints to ensure adherance to the new plan exist. I urge the Subcommittee to facilitate action by the appropriate legislative and regulatory entities to ensure that these independently contracted distributors, so-called counselors, are compelled to market these products responsibly, or not be allowed to handle these products at all. Laws should exist to make CPI liable and accountable for the actions of it's distributors. Having worked closely with these counselors, I know that the policies of the company frequently are not the basis for activities in the field. As is clearly evident from the testimony during these proceedings, lay marketing of healthcare products, when distributors are allowed freedom to abuse products at their disposal, is potentially catastrophic. Furthermore, the enacted legislation and policies should be sufficiently broad to govern the activities of lesser known companies and products.

Chairman ROTH. At this time, I would like to call forward Patricia Stombaugh and Greg Martin. Please raise your right hand.

Do you swear the testimony you will give before the subcommittee will be the truth, the whole truth and nothing but the truth, so help you God?

Ms. STOMBAUGH. I do.

Mr. MARTIN. So help me God.

Chairman ROTH. I want to welcome both of you and thank you for being here. I appreciate the fact you did so at some sacrifice. I welcome both of you. As I understand it, you both have been distributors of Herbalife, and we are particularly pleased to have you here since both of you are from my State of Delaware. What I would like to do is ask each of you to make your opening statement, and then I will have questions for you. Ms. Stombaugh?

TESTIMONY OF PATRICIA STOMBAUGH, CURRENT HERBALIFE SUPERVISOR, SMYRNA, DE, AND GREG MARTIN, FORMER HERBALIFE DISTRIBUTOR, DOVER, DE

Ms. STOMBAUGH. First, Senator, I don't mean to be disrespectful or facetious, this is the first time I have been to a hearing like this, and I have a question. I am rather surprised and I know the Senators are very busy, but there were Senators here that seemed very interested, made quite a few statements, and I am just wondering why they are not here to hear the whole story?

Chairman ROTH. Well, that is unfortunately—you mean on the panel?

Ms. STOMBAUGH. Yes.

Chairman ROTH. There are many demands on the Senators' time. Some of them serve on other committees. Unfortunately, they try to divide their time. That is one of the reasons why we have a written record so that the entire record can be reviewed.

Ms. STOMBAUGH. OK. My statement is: My name is Pat Stombaugh. I am a resident of Smyrna, DE. I own a travel agency; I manage 120 townhouses. I serve on the Smyrna Town Council, and I am also a consumer and distributor of Herbalife.

In August 1984, I was introduced to Herbalife. I wanted to lose weight and improve my nutrition. After taking Herbalife for 2 months, losing 5 pounds and feeling much better, my friends began to ask for more information about Herbalife. Five of them decided they, too, wanted to try the product. At this point, I decided to become a distributor.

As my friends began taking Herbalife and having good results, they referred their friends, and within 2 months, I became a supervisor. I have very little time to devote to the sales of Herbalife being a single parent with a 6-year-old son. Therefore, I am not one of the big moneymakers. My sales have increased due to the referrals of satisfied customers. Between myself and those to whom I distribute it, we have sold Herbalife to over 300 people. Herbalife has worked for me, and it has worked for my customers. We know the product works and that it is safe when taken as recommended. I would never—never—sell any product to any person if I thought in any way it would harm them.

I personally know many people who have stated their health has improved by following the Herbalife program. I don't believe that people on Herbalife are making medical claims for the product. Many of the people have overweight problems or inadequate nutrition. If these problems can be solved, health changes normally follow. I believe the people who said they felt better using the Herbalife products are stating the facts—their health problems improved through weight loss and sound nutrition. They are not saying that Herbalife is like a medicine that cures a disease. No one I know has ever claimed this.

Senator Roth, I really would like to change sides now and kind of put on the political hats since I am a political figure, too. I have more at stake here today than just being here on behalf of Herbalife. I have got to go back and face people that I represent, also. I am a councilwoman for the Town of Smyrna, and you are the U.S. Senator, and I think both of us were elected by the people to our offices. The people have placed their trust in us to act on their behalf and for their interest. Our people deserve the truth and they need some of us to stand up for them.

Herbalife has helped millions of people. I feel each of us should have the right to choose if we want to use it or not. I feel from the information I have been given, and I have collected, we, the Herbalife people, can hold our heads up high and wear our pins proudly.

I would like to thank Senator Roth and the subcommittee for the opportunity to present my views on Herbalife.

Chairman ROTH. Thank you. Then I would ask you, Mr. Martin, if you would proceed with your statement.

Mr. MARTIN. Thank you. I am pleased to have the opportunity, of course, to be here today. My name is Greg Martin, and I live in Dover, DE. I first began using Herbalife products in September 1984. I suffered no ill effects from the products and lost about 13 pounds in 3 months time and I felt better than I ever had in years. I, and along with my wife, began selling the products in October 1984. We eventually sold Herbalife products to approximately 100 customers, including the customers of 10 distributors which we eventually had under us.

Most of my customers suffered from constipation when using Slim and Trim Formulas No. 1 through 4. In spite of the constipation, a majority of my customers were satisfied with the weight lost. However, about 10 to 15 percent of my customers had other problems. One woman, the wife of a doctor, had a reaction to NRG. She checked with her husband and found out NRG contained caffeine. I was surprised when she told me this because this was the first time I was aware that NRG contained caffeine.

Several of my customers suffered from vomiting from taking the products, and one woman became so ill she had to miss work and was sick for 3 days. One customer who had two previous heart bypass operations was taking Herbalife because I understood from the literature that it was good for heart problems. This man became extremely constipated.

As a result of these reactions, I called Herbalife headquarters on January 8, 1985. I asked if there were any medications that would preclude the use of the Herbalife line and what reactions a customer could expect from the use of the products. I was told simply that

Herbalife is a food company and not a drug company, and that I should not be practicing medicine, and that I should contact my supervisor.

I had already talked to my supervisor and a number of other supervisors, and they had no answers.

I also had requested information about possible reactions to Florafiber for people who had colitis. Again, I was simply told to talk to my supervisor.

As a result of these experiences, I stopped selling Herbalife products to retail customers at the end of February 1985. I do not want to be associated with a company who claims its products are safe for everyone to use and then will not deal with the problems as we experienced them.

I am convinced that diet products and food supplements can do a lot of good. I would not want to see them prohibited. However, I think that some standards should be established and that the FDA should enforce these standards so that the public can be confident that these products are safe.

And may I add, Senator Roth, a couple of extemporaneous remarks of some of the things I heard here today. I do not consider myself to be a selfish entrepreneur. I am very concerned with the reactions of the people that I deal with and the complications they are finding. However, in spite of some of the experts' testimony, I draw a parallel to the experts' testimony and opinions they had in the early 1970's when the foreign cars came on the market and advised not buying them because they were unsafe, they were going to be collapsing in an accident, so forth, and the people continued to buy the foreign cars in spite of what the experts said for one reason—they worked.

That is the reason why I represent and still use products with a low-calorie diet because they work. Thank you.

Chairman ROTH. Thank you, Mr. Martin. Ms. Stombaugh, may I ask you, if I recall your testimony, you sell to roughly 100 customers; is that correct?

Ms. STOMBAUGH. What I gave was a figure of 300, the figure of myself and the people who sell under me. It is a group volume figure.

Chairman ROTH. Have any of your customers experienced any problems?

Ms. STOMBAUGH. I had one customer who had constipation, which I find a little surprising today because all the testimonies I have heard from the doctors said there are so much diuretics in the products, if there is so much diuretics in the products, why are they having the constipation rather than diarrhea?

Chairman ROTH. Let me ask you this question. Do you agree accurate information should be available regarding the safety of ingredients?

Ms. STOMBAUGH. I certainly do.

Chairman ROTH. Did you both obtain a blue booklet or a pink booklet?

Ms. STOMBAUGH. Senator Roth, I take full responsibility for the copy of that book. If Herbalife wants to take away my distributorship, I guess I deserve it. I did not know that was not an Herbalife product. It was given to me by another distributor. When I was—

Friday was the first time. I had called and asked if a group of people from Herbalife could come down and talk to you or one of your aides. We just wanted to be able to talk to someone to give our viewpoint. Mr Rinzel called me about Wednesday of last week, and we were granted time to come down and talk to him on Friday so I didn't have much time to ask many questions or get information together. I assumed myself that that book was from Herbalife, which it is not. Some of the information that is in it I have found out since that that was in the book that has been redone, the book Herbalife has redone. I don't feel Herbalife can be held responsible in any way for that book no more than you or Mr. Rinzel or anybody else in this room. We cannot control what people do out on the streets.

Chairman ROTH. Could I ask you this. When did you receive this book?

Ms. STOMBAUGH. I got a copy of the book about 2 months ago.

Chairman ROTH. When did Herbalife tell you that it was not an official document?

Ms. STOMBAUGH. Friday when I left Mr. Rinzel, I went over to—well, Kendall Associates office. I had been talking with one of the gentlemen there. He said since our group was coming to Washington to meet with Mr. Rinzel that they felt they should at least meet us. We were very surprised when we got over there. Mark Hughes and the doctors were there, and we did not know they were going to be there, so that was kind of a pleasant surprise for us.

Chairman ROTH. Have you seen any other copies of this?

Ms. STOMBAUGH. Of that book?

Chairman ROTH. Of this book.

Ms. STOMBAUGH. No, I haven't.

Chairman ROTH. Mr. Martin, have you obtained a training booklet of any type?

Mr. MARTIN. Yes, sir; the type that is right in front of you, or that you are holding, actually.

Chairman ROTH. Where did you receive yours?

Mr. MARTIN. From my supervisor.

Chairman ROTH. Has anyone advised you that this is not an official document of Herbalife?

Mr. MARTIN. They didn't need to. I believe on the front page, actually on the cover, there is a disclaimer down there at the bottom.

Chairman ROTH. "This booklet is not official literature, but merely a guide to be used for informational purposes."

What did you understand to be a "guide for informational purposes" to mean?

Mr. MARTIN. I understood it to be a number of people who had experience with the product, correlating their experiences with other people and bringing those experiences together in a comprehensive report such as you see before you.

Chairman ROTH. Both of them have at the top, "The Amazing Magic of Natural Herbs." And in there there are a number of statements, such as, "can be effective in some types of asthma." "Guarana, naturally increases energy, mental alertness, provides a natural lift." It says, "Cellulite product," and talks a little bit about breaking up fat.

Let me ask you this. Did you ever use any of this information here to discuss your sales?

Mr. MARTIN. Yes, I did.

Chairman ROTH. Did you ever refer to this booklet in making your sales?

Ms. STOMBAUGH. The first and the second page, when it talks about calories. Most everything is spelled out in the Herbalife literature that they supply to you, and I didn't have to refer to it too often, but I did refer to the, I believe it's the first or second page where it has the calorie breakdown, which, Senator Roth, I would like to say one other thing on the calorie breakdown.

I am very much opposed to us being kind of—what is the word I want—with Cambridge, being compared to Cambridge. Cambridge is a very low calorie diet, I believe. It is recommended 330 calories a day. I am not a pharmacist; I don't have any kind of degrees. The information I have gathered, I have been told that 400 calories is considered malnutrition. On all of the Herbalife literature, including the can of the No. 1 Formula, it states at the bottom that the Herbalife products are recommended with a minimum of 1,000 calories a day, and I also went to the health department in Dover and got a copy of their recommended diet down there, and their recommended calories for daily requirement would be between 1,000 and 1,200.

Chairman ROTH. We are covering, as you know, several different products, as is typical of this kind of a hearing.

I will include both of these booklets as part of the record as exhibit No. 10.

[See p. 327 for exhibit No. 10.]

Chairman ROTH. Let me ask you, Mr. Martin, you say a number of your customers did have reactions to taking the product.

Mr. MARTIN. Yes, they did.

Chairman ROTH. What did you recommend that they do?

Mr. MARTIN. It depends. If it was just constipation, I recommended they drink more water, or there is a product on the market called unprocessed bran, which can be bought in any nature store, nutrition store, and I also recommended they add that to their diet along with the Formulas 1 through 4.

The vomiting, I told them immediately get off the product, and I refunded their money.

Chairman ROTH. Would you agree that it would be desirable for the appropriate Federal agencies, such as FDA, to make an analysis, a test of these products to ensure their efficacy and safety?

Mr. MARTIN. I would agree with it, that the ingredients would be labeled up there on the top, but if the FDA is going to be looking at these products with the intent of prohibiting or at least confining the sale or use of these to the medical profession, I would be against it.

Chairman ROTH. Would you care to comment?

Ms. STOMBAUGH. I would be very much against it being regulated by either physicians or pharmacists. One of the reasons I feel—not to discredit doctors or anything like that. I haven't been to a doctor yet who has handed me a prescription and sat there and explained the use of the prescription to me. When I have taken it to the drugstore, I hand it to the cashier; she hands it to the pharmacist; he fills it out, types a few words on the label; gives it back to me.

I think there is more information given by the market plan that is used now than information that I have gotten on prescriptions from pharmaceutical——

Chairman ROTH [interposing]. Do you agree that it is appropriate for FDA to test drugs before they are marketed?

Ms. STOMBAUGH. Yes, I do. I would like to say this about that. Of course, there are two sides. Since Friday, I have heard a lot from both sides. The only thing I can do is sit down and try to sensibly use some common sense. I don't have anything else to do with and try to come up with some conclusions.

Like I say, this all happened on Friday, and I haven't really had a chance to sit down and get a lot of answers to some questions that I have. I don't know if Herbalife had their product tested 5 years ago. If they didn't, I feel this way:

I suppose there is some special university or something that it has to be tested through. I don't know who is supposed to do this testing. I feel over 5 years of use with millions and millions of people that have used it, what more can be said in a test or university?

There is an alleged, I think somebody said somewhere, alleged four deaths. They stated this one woman. I understand she smoked heavily; she drank coffee; why didn't the news article say she smoked X brand of cigarettes. Right on the cigarette packet it tells you it is hazardous to your health. Why didn't it state she drank X brand of coffee? Coffee has got caffeine in it. Why didn't it state those things? Why did it have to say Herbalife? They do not know the cause of that death. That has not been proven as far as we know right now. We don't know what the results of the autopsies were.

I feel out of 5 years of use and millions and millions of people that have used it, if there was something harmful in this product, I can't believe that if, if in fact four people did die from something in Herbalife, how could only four out of the millions that have taken that—I can't buy that. I don't buy that.

Chairman ROTH. My last question is, do you agree that it is desirable that the consumer have accurate and full information about the products?

Ms. STOMBAUGH. Yes, I do. I certainly do.

Mr. MARTIN. Senator Roth, my interest in nutrition goes all the way back to 1965 when I went to the University of North Carolina, the hospital, where I was a student with bleeding ulcers and required in the next few days 5 pints of blood. They took tremendous care of me because we were conducting experiments down there. Five years later I had a recurrence of ulcers. They wanted to hospitalize me. They put me on a milk diet and only to find out I was allergic to milk, and they had no other alternative. I am hypoglycemic; I can't eat candy; drink milk; there are some types of food and vegetables I cannot take.

My interest in nutrition began as a result of reactions to food, which I was not getting any direction from doctors. Not to downplay the role of doctors, they certainly saved my life in 1965. All I am saying, there are many people out there like me who hear conflicting reports, who knows how their body feels and reacting and given a product like this and feel better and they are gung-ho for it. That is why I am gung-ho for these products.

Ms. STOMBAUGH. That is another thing about that, one of the doctors was testifying, they were saying they did not believe the product worked; that less than 30 percent would work. Senator Roth, you know how many letters and phone calls you have gotten, and I know how many people I have sold the product to. I can't explain the content; I can't explain what it does. All I can explain is it has worked. Has anybody in this room taken Herbalife? How can people sit up here and say it doesn't work if they haven't taken it? Facts are facts to me, and that is what I am looking for. I am looking for the facts. I am out there selling these products. I want to know and the information that I have been given this past week, I am walking out of here feeling that Herbalife is the best product on the market, and I have no hesitation to sell it. I really don't. If there is anyone in the room maybe they can speak and whether it worked or not.

Mr. MARTIN. I feel the company, if they are vitally interested in things, they should be taken to task—the individual companies, rather than a wholesale scale and lump everything together.

Chairman ROTH. I do understand, Mr. Martin, in your case, one of the reasons you quit selling, you were concerned, for example, NRG did contain caffeine.

Mr. MARTIN. I was very concerned.

Chairman ROTH. In other words, you do think it is critically important there be accurate information?

Mr. MARTIN. I do.

Ms. STOMBAUGH. Senator Roth, can I say one other thing. I hate to do this, but I feel it is necessary. I feel there are facts that need to be known, and I am sorry, Mr. Martin, but I am from Dover; Mr. Martin is from Smyrna. He says he was a distributor for Herbalife. We checked the Herbalife computers, and he is not registered as a distributor or supervisor. I also found out that there is another product on the market that came on the market in December or January. Mr. Martin has started selling that product. He became an ambassador for that company the beginning of February. He says that he at the end of February, that he no longer wanted to be associated with Herbalife. I know for a fact that he got some products from one of my downline last week for a customer, and I hate to discredit anyone, but I think the facts need to be known.

Chairman ROTH. Mr. Martin?

Mr. MARTIN. I am glad to get the opportunity to respond, Senator Roth. I think Mr. Rinzel and I discussed this. At the point of her making mention that I am not listed as a supervisor, my wife was originally on the application, and I was the one that was selling the product. This may seem farfetched, but neither of us, including the supervisor, realized that my name was not on the application. As soon as that became known and apparent to us, I sent a letter with a return receipt requested, and I provided Mr. Rinzel with a copy of that, that my name be added, along with my wife's to the Herbalife records.

Chairman ROTH. Be added to what?

Mr. MARTIN. To the Herbalife records. Herbalife, in fact, called me last week to verify something. The question they had about the application that I sent in a month ago when I was totally dealing with Herbalife. They also made inquiries of several people in the month of January when I was also qualifying for supervisor, and so they called a number of people around so they are aware somewhere that my name is on the list. They didn't call my wife; they called me. And I told Dan technically and officially, the supervisor is listed in my wife's name.

Now, as regards to the buying of the product from Patricia's downline, I said in my opening statements that I do not sell personally to retail customers. However, when the people signed up under me as a distributor, I had thought I had the obligation if they chose to remain to sell Herbalife products, not only tell them about my particular findings, but since they were looking to me as a supervisor, but as a distributor in order to get the products, I fulfilled that obligation so the products I got went to another distributor.

I personally have not sold Herbalife to a retail customer since February.

As regards to my being with another organization, that's true, but I was not even aware of the organization until February 25, 1985, at which time we had already made a decision that myself and my supervisor above me, that we would no longer represent Herbalife and that is the reason we looked for another company, and at the end of February, that was going to be it for both of us. Thank you.

Chairman ROTH. Thank you. If we have any further questions, we will submit them to you in writing. I appreciate again both of you being here today.

Mr. MARTIN. Thank you.

Chairman ROTH. Our final witness if Leo Daboub. Will you come forward, please? Raise your right hand.

Do you swear the testimony you will give before the subcommittee will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. DABOUB. I do.

TESTIMONY OF LEO DABOUB, NEWPORT BEACH, CA, ACCOMPANIED BY CHARLES ABBOTT, ESQ.

Chairman ROTH. Would you introduce yourself and say who is accompanying you and in what capacity?

Mr. DABOUB. To my right is my attorney Charles Abbott, and he represents me legally in every aspect of all my companies.

Chairman ROTH. Would you please briefly describe—I understand you have no prepared statement; is that correct?

Mr. DABOUB. That is correct.

Chairman ROTH. Would you briefly describe your educational and work background to us and then explain how you became involved in the diet product business?

Mr. DABOUB. Basically, I am an entrepreneur, and I am very proud to say that word. Today I heard some statements putting entrepreneurs a little bit down. I think entrepreneurs are the people who work the free enterprise system. Responsible entrepreneurs, which I think I am, usually try to comply with the ethics of law as much as we can. That is very difficult sometimes because the law has many interpretations.

To go back a little bit, I started mail order in selling vitamins and then I switched it to weight-loss products. Now these weight-loss products are products that I right now represent are basically, there are basically scientific medical studies backing them up. Two of them have even been labeled by a panel appointed by the Federal Government, FDA, as safe and effective.

I am very proud to say that because the studies of the doctors or the nutritionists you would want to hear about.

Chairman ROTH. Let me ask you, have you had any formal training in nutrition?

Mr. DABOUB. No; none whatsoever.

Chairman ROTH. Now, I understand you recently decided to discontinue your mail order business. Can you tell the subcommittee why you made this decision?

Mr. DABOUB. Well, basically, it was a matter of interpretation; it was a matter of so many regulations in the Postal Office that even—every advertisement that was going to be issued was revised legally by my attorney and was answered to me, it is OK to run it. The Post Office was more interested in the interpretation studying what the ad was saying. So I read the fine line and I understand they didn't like mail order business at all.

Chairman ROTH. Would you say from you experience that the mail order diet business is a lucrative, profitable one?

Mr. DABOUB. It was. Right now, there are so many regulations, so many bad publicity. I think the consumer is very confused. I think the consumer doesn't know what really is good and cannot say what product is good and what product is bad. I left it in the air.

Chairman ROTH. Would you say your ads have contributed to the confusion due to their claims?

Mr. DABOUB. I honestly don't feel so. I feel there are some very bad products on the market, but I feel that my products, as I said 1 minute ago, have scientific medical studies that they work and are safe.

One thing, if I can say so, Mr. Chairman, we have heard some testimony from doctors and nutritionists. But I feel personally there is a conflict of interest. I feel somehow that many doctors and many nutritionists are making their living out of weight loss, and they hate to see a product which is labeled to be safe and effective selling for a very low price, and those are potential customers taken away from diet clinics and from many other institutions.

Chairman ROTH. Is this one of the materials you sell, Energetic Contour Cream?

Mr. DABOUB. No, not anymore, Mr. Chairman. That product was discontinued some time ago. As soon as we noticed that there was no feedback from the customers—we always have feedback from the customers telling us if it is good or bad; "I want my money back," or, "I lost inches," or, "I lost weight." This product had no feedback.

Chairman ROTH. You did sell this?

Mr. DABOUB. I did sell it. I had some studies I was provided by a laboratory and there were some expensive clinics in Beverly Hills that are using it with a wrapping. It was not on my line of products, so I discontinued it with nobody asking me to do it.

Chairman **Roth**. What was the claim for this material?

Mr. **Daboub**. The basic claim was not a weight loss, but a reduction in measurement, around the waist.

Chairman **Roth**. A reduction in measurement?

Mr. **Daboub**. Yes.

Chairman **Roth**. What scientific basis was there for this claim?

Mr. **Daboub**. I have the studies. I cannot recall right now exactly, but more or less they were based on the fact of the wrapping and they call it hot oils, and that they mobilize the fat tissue so they can shrink a little.

Chairman **Roth**. Can you tell us any difference between this cream or any other body and hand cream?

Mr. **Daboub**. Scientifically I can't because I'm not an expert.

Chairman **Roth**. Could you tell the subcommittee why you have not fully complied with the books and records subpoena issued over 6 weeks ago that asked for the names and addresses of all persons used by you in your testimonials?

Mr. **Daboub**. Because they told us not to.

Chairman **Roth**. Who told you not to?

Mr. **Abbott**. Mr. Chairman——

Chairman **Roth** [interposing]. You are not under oath.

Mr. **Abbott**. As the attorney, I am the only one who knows the answer to that because I was the one who received the communication. That specifically was my instruction.

Mr. **Rinzel**. Mr. Chairman, I would suggest——

Mr. **Abbott** [interposing]. It weighed about 400 pounds and I was told not to send it until I was given instructions as to where and when to send it.

Mr. **Rinzel**. If the attorney wishes to give a statement, I would suggest, Mr. Chairman, he be placed under oath.

Chairman **Roth**. Please rise. Do you swear the testimony you will give before this subcommittee will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. **Abbott**. Yes, I do, Mr. Chairman. Mr. Chairman, with respect to the list of customers, I had the computer house which has that list on disks stay up all night long to run that list off and at the time I met with Mr. Rinzel, I told him that was available but I had not brought it with me to the hotel because it weighed I think it was 200 or 300 pounds——

Chairman **Roth** [interposing]. That is not the question.

Mr. **Abbott**. Excuse me; I am going to answer the question.

Chairman **Roth**. Let me redirect the question. The question is, why hasn't Mr. Daboub complied with the subpoena which requested the names and addresses of all persons used by him in testimonials? I am not asking for customers.

Mr. **Abbott**. I am sorry; I thought it was customers you asked for.

Mr. **Daboub**. That was provided to Mr. Rinzel over 2 weeks ago.

Chairman **Roth**. You say that was supplied?

Mr. **Daboub**. Yes.

Chairman **Roth**. A full list?

Mr. **Daboub**. To my understanding it was a full list.

Chairman Roth. I understand from reviewing your deposition, which I will place in the record, that you believe the cream, Energetic Contour Cream, does not cause a person to lose weight but it does cause fat to be shifted around the body. Can you explain how this fat is shifted by using this cream?

We will place the deposition in the record as exhibit No. 11.

[Exhibit No. 11 may not be found in the files of the subcommittee.]

Mr. Daboub. Basically, Mr. Chairman, I will love to explain it to you, but I am not an expert. The only thing I know is the tightening of the wrapping with the solution of hot oils, so-called that way, produces those results.

Chairman Roth. But you did sell that in your retail stores then not knowing whether or not there was any truth to those claims?

Mr. Daboub. Well, the studies that were provided to me by a laboratory that claimed it had this product for more than, I think, 10 years; it's the same basic product that wrapping clinics are using at the present time. We voluntarily discontinued this product because, as I said before, we had no feedback from our customers.

Chairman Roth. Who supplied the scientific test to you?

Mr. Daboub. The laboratory, Ramma Institute.

Chairman Roth. Who was that?

Mr. Daboub. Ramma Institute.

Chairman Roth. Is that the manufacturer of the material?

Mr. Daboub. Yes, Mr. Chairman.

Chairman Roth. What about your Orgi-nine product, how much hormone is produced by taking this product as directed?

Mr. Daboub. Again, I am not able to say the exact amounts of growth hormones that are released. The only thing I can cite is the studies we have provided, and we have provided those studies to give government agencies so they can review it and those studies, some of them, indicate that when ornithine and arginine are intravenous, they do not release growth hormone as effectively as when taken as a tablet.

Chairman Roth. I would like to point out you are marketing products which are designed to be taken by persons internally or, in some cases, to be applied directly on the body. What sort of responsibility do you believe you have to ensure the safety and efficacy of these products?

Mr. Daboub. The different studies, when a product is presented to me, as I said before, I am not a nutritionist and I don't intend to be one, when they presented me some products, laboratories, they present me with sufficient studies. The products that don't have sufficient studies, I reject and those studies sometimes are published studies of journals and some are very reliable by competent medical doctors.

Chairman Roth. You sell these products through retail stores; is that correct?

Mr. Daboub. Right; at the present time, retail stores.

Chairman Roth. How many of those do you own or operate?

Mr. Daboub. Well, we have eight old stores and there are a number of 22 all together including franchises.

Chairman Roth. What do the total sales of these stores amount to?

Mr. DABOUB. It varies very much, Mr. Chairman. I think they have dropped down significantly in the last 3 months because of the adverse publicity.

Chairman ROTH. What was the peak of sales?

Mr. DABOUB. For a particular store, could be maybe——

Chairman ROTH [interposing]. All right, for a particular store.

Mr. DABOUB. Average store.

Chairman ROTH. Give the range for the stores.

Mr. DABOUB. I would say an average store would be selling in the vicinity of $25,000 to $30,000.

Chairman ROTH. A year?

Mr. DABOUB. A month.

Chairman ROTH. Did you make any scientific tests yourself to determine the safety and efficacy of these products?

Mr. DABOUB. I am going to answer that question with a special remark. I have been asked that question several times, and I don't understand how a businessman, every product that is presented to me should do that, if we have and we rely on competent medical studies. Our tests will be insignificant completely against those studies. There are people who have spent a lot of money, universities that have spent a lot of money in producing those studies.

Chairman ROTH. Let me ask you this question. This so-called Energetic Contour Cream, did you really believe, can you really believe that this material would do what you claim it did or what you claimed it did?

Mr. DABOUB. I believe that the product would reduce a measurement of a person who used it properly, but there was no weight loss and if you ask me a question like that, I would answer it this way:

Energetic Contour Cream right now is the only product that I reject ever marketing, and we marketed for a very limited time only that product, but I did believe that it reduced the measurement, not reduce the weight loss.

Chairman ROTH. Let me ask you about this Fast-Trim. Is this basically a PPA product? If this is the case, what is new about it or discovered? PPA products have been on the market for years.

Mr. DABOUB. Yes, Mr. Chairman. It is new because we have packaged it a different way and includes a herbal diuretic; it includes a 1,200-calorie diet plan; and it includes a mental conditioning program.

Chairman ROTH. Let me ask you, how does this product burn off fat? Isn't it merely an appetite suppressant?

Mr. DABOUB. The product is an appetite suppressant, and what happens is the only real way to lose weight is by reducing your calorie intake. Now, the mistake I have listened to here several times is they are trying to classify diet products as worthless because they don't see it as an aid. How many people can follow a 1,200-calorie diet plan without having a need?

Chairman ROTH. Didn't some of your ads claim that it would burn off fat?

Mr. DABOUB. Yes, Mr. Chairman. The body burns the fat.

Chairman ROTH. Isn't that inaccurate? Isn't that a falsehood? Is that a proper statement that it burned off the fat? Isn't that misleading the consumer?

Mr. **Daboub**. I don't think it is misleading; the end result is what is going on. The person will be burning fat as soon as they have this caloric deficit.

Chairman **Roth**. That is not as a direct result of the material, is it; it is because they are not eating?

Mr. **Daboub**. There are two ways to point that. If I give a person a 1,200-calorie diet, I am positive that that person will not follow it. It is not easy to follow. But if I gave them my product or any other product that has an appetite suppressant, it will be much easier.

Now, I am not saying that because that is what I think. I am saying that because that was demonstrated in several studies.

Chairman **Roth**. Let me ask you this, Mr. Daboub. Isn't is true that your ads for the products have been discussed and found to be false and misleading by an administrative judge of the Postal Inspection Service?

[Witness conferring with counsel.]

Chairman **Roth**. Yes or no.

Mr. **Daboub**. I hope it is easy to say yes or no. It has been a business decision. The Postal has approached us several times with a proposal of a consent agreement admitting no guilt. Now, we have signed those because there is no way of fighting them. We believe that our ads have not been misleading and we have corrected——

Chairman **Roth** [interposing]. In other words, you believe this material really does burn off the fat; is that what you are saying?

Mr. **Daboub**. I believe that in conjunction with our packages, yes, the person will burn off the fat.

Chairman **Roth**. Just let me say in closing, I, like you, have a great respect for entrepreneurs. I think they are vital, important, and provide a great service. But I think they also have a responsibility, a responsibility to deal truthfully with the consumer, and let them know what the facts are, and I am sorry, I just find this material an outrageous example of what shouldn't be, of misleading the innocent.

I have no more questions. Do you have anymore?

Mr. **Rinzel**. No questions.

Chairman **Roth**. You are excused.

Mr. **Abbott**. I was told, Mr. Chairman, that we would have an opportunity to make certain corrections in the transcript of the deposition before that would be entered. We just received the transcript the other day. I only have three. I could put them in the record.

Chairman **Roth**. You can work that out with the staff director.

The committee is in recess until 10 o'clock tomorrow morning.

[Whereupon, at 1:25 p.m., the subcommittee recessed to reconvene at 10 a.m., Wednesday, May 15, 1985.]

WEIGHT REDUCTION PRODUCTS AND PLANS

WEDNESDAY, MAY 15, 1985

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD-342, Dirksen Senate Office Building, under authority of S. Res. 145, section 13, dated May 3, 1985, Hon. William V. Roth, Jr. (chairman of the subcommittee) presiding.

Members of the subcommittee present: Senator William V. Roth, Jr., Republican, Delaware; Senator Warren B. Rudman, Republican, New Hampshire; Senator William S. Cohen, Republican, Maine; Senator Lawton Chiles, Democrat, Florida; and Senator Albert Gore, Democrat, Tennessee.

Members of the professional staff present: Daniel F. Rinzel, chief counsel; Eleanore J. Hill, chief counsel to the minority; Katherine Bidden, chief clerk; Glenn Fry, investigator for the minority; Carolyn Kulisheck, staff librarian; Sarah Presgrave, executive assistant to the chief counsel of the majority; Howard Shapiro and Barbara Kammerman, staff counsel; and Cindy Comstock, Carla Martin, and Townsend Feehan, staff assistants.

[Senators present at the convening of the hearing: Senator Roth and Rudman.]

OPENING STATEMENT OF CHAIRMAN ROTH

Chairman ROTH. The subcommittee will please be in order.

Today the Permanent Subcommittee on Investigations will conclude its hearings on weight reduction products and plans. Yesterday, the committee heard from a variety of witnesses. We heard expert testimony about dieting in general—specific diets, diet products, and therapeutic and toxic effects of various herbs. We have heard from a mail-order diet entrepreneur. We heard criticism of the misuse of the Cambridge product, criticism of the Herbalife line of products, and we also heard a Herbalife distributor endorse and recommend the Herbalife line of products.

The evidence presented yesterday provides a background for today's witnesses as many questions were raised yesterday from the basic question of whether Government should be involved at all in this area as to whether specific products' ingredients are safe and effective. Perhaps our witnesses today can help answer those questions which arose yesterday, particularly FDA Commissioner Young.

Dr. Young will be our first witness and will be followed by Vaughn Feather, the president of Cambridge Plan International, and Mark Hughes, founder and president of Herbalife International.

We attempted yesterday to place a large amount of information into the record, but to ensure that we have a complete hearing, the record will be kept open for a period of 2 weeks to receive additional statements or responses to written questions.

At this time I would call forward Dr. Young. Dr. Young, would you introduce who is accompanying you?

Dr. YOUNG. Thank you, Mr. Chairman. I have on my right Mr. Tom Scarlett who is our general counsel. On my left Mr. John Taylor who is in charge of compliance of foods, and further on my left, Dr. Allen Forbes who is our leading nutritionist in the Center for Food Safety and Applied Nutrition. We all thank you for being here.

Chairman ROTH. Under the rules of the subcommittee, we require all witnesses to be sworn. So would you and your colleagues please stand and raise your right hand?

Do you swear the testimony you will give before this subcommittee will be the truth, the whole truth and nothing but the truth, so help you God?

Dr. YOUNG. I do.

Mr. SCARLETT. I do.

Mr. TAYLOR. I do.

Dr. FORBES. I do.

Chairman ROTH. Please be seated. Dr. Young, we have your prepared statement. Because of the interest in moving as expeditiously as possible, I would ask that you summarize your statement, and we will include it in its entirety as if read.

TESTIMONY OF FRANK E. YOUNG, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY THOMAS SCARLETT, GENERAL COUNSEL; JOHN TAYLOR, DIRECTOR, OFFICE OF COMPLIANCE; AND ALLEN F. FORBES, M.D., DIRECTOR, OFFICE OF NUTRITION AND FOOD SCIENCES

Dr. YOUNG. Thank you very much, Mr. Chairman. I will only make a few points dealing with the summary that may be good in starting off and augmenting your excellent summary from yesterday's meetings.

We believe that many individuals in the United States are overweight, perhaps as many as 20 million, and the basic mechanisms by which obesity occur are manyfold. One mechanism appears to be the increased intake in relation to output, another is a decreased exercise, and also metabolic factors dealing with the metabolism of food stuffs and endocrinological factors enter in. So obesity is a complicated field in which there are many causes to the overall clinical findings of overweight.

The best general strategy for weight reduction is a curtailment of calories. This can be done in a variety of ways. My testimony deals with some of the issues that are described in the appropriate reduction of caloric intake.

In addition to counting calories, we feel that it is most important in a general strategy of weight reduction to modify an individual's behavior. The combination of a 1 to 2 pound reduction per week, coupled with a behavior modification of determining what are the best food products that one can utilize in a lifelong career of curtailing weight is the most important strategy.

Over the years, dietary strategies have also been augmented by some medicinal compounds. Two examples cited in my testimony are phenylpropanolamine and benzocaine, compounds that have been used to augment the general dietary strategy.

In addition to the products that have been proved safe and effective, a number of other compounds have been brought to the market which we have dealt with and, Mr. Chairman, I believe yesterday you demonstrated one of my favorites, a pair of eyeglasses with two tinted lenses that were supposed to, by the mere wearing of these glasses, curtail appetite.

And perhaps because so many of us are overweight and the problems of overweight, coupled with our desire to look slim, trim, prolong life, has led to a number of compounds that have come on the market that are less effective, and FDA has taken action against those.

The very glasses that you describe, some of the electric stimulating devices, and those curtailing body fat by the equivalent of 3,500 situps by a mere shot of electricity has done very little beyond trimming the weight in one's pocketbook. So there are problems with some of these medical devices.

Also, there have been problems in relation to products that have made unsubstantiated claims, and I have listed a number of these in my testimony, and I will only highlight a few that FDA has acted on. Starch blockers, tablets prepared from beans that were designed to essentially block the digestion of starch and, therefore, curtail weight; the recent action that we took on the dehydroepiandrosterone, a steroidal hormone derived from human urine; the cholecystokinin hormone involved in human digestion sold by mail and retail stores that claim to decrease hunger and cause sudden and dramatic weight loss—we felt there was not adequate information dealing with those. Or, similarly, human chorionic gonadotropin mixtures that have been sold or mixtures of amino acids as arginine and ornithine, that were allegedly involved in stimulating human growth hormone.

Many of these compounds, as well as glucomannan, which is derived from a konjac root, are designed to deal with both food supplements and drug plans, and it is in that arena that FDA has its hardest problem in dealing with the way in which we look at food and drug regulation.

For example, the problem of the food product for which claims may be made that cause it to be a drug is not a unique one and brings us to the heart of this dilemma of determining how to best regulate products in weight loss.

This really is true also in vitamins, minerals, and herbal products. Vitamins and minerals and chemicals that are only needed in small amounts, yet when a person goes on a very substantial diet plan, one may be depleted in vitamins and minerals and supplements are, under those circumstances, appropriate.

Herbs are used in a variety of products throughout the country—teas, foods, also in drugs. Some of the medicines that were derived originally came from herbal products. So the appropriate use, not the misrepresentation, of herbs is an important factor and one that I am pleased that you are considering here.

The regulatory strategy that we take is as follows. After careful examination we review thoroughly the course to be taken and follow either with regulatory letters, injunctions, seizures, rulemaking as our major instruments. Each of these are tailored to meet the particular concern at hand.

Some of the products that I mentioned earlier have already received regulatory letters.

Let me conclude by saying: What does it take to lose weight? The best cure of overweight is undereating. And it is a major problem that has to be clearly addressed. Caloric intake in excess of a caloric need is the dominant cause of overweight. When it comes to weight loss, we suggest that the following basic principles are important:

First, consult a physician and, if possible, a dietician before embarking on any very restrictive diet. I emphasize "very restrictive diet."

Aim for moderate weight loss, 1 to 2 pounds per week.

Reduce the portion sizes, but maintain a balanced diet from the four basic food groups—grains and cereals, dairy products, fruits and vegetables, poultry and fish.

[At this point in the hearing, Senator Chiles entered the hearing room.]

Dr. Young. Limit the intake of alcohol, fats, sweets, and high-caloric foods and exercise regularly. Keeping one's weight constant or appropriate is a lifelong task. It does require behavior modification when one is undergoing a severe diet regimen and, therefore, the combination of caloric reduction and behavior modification are the best medical procedures for reducing weight. Thank you, Mr. Chairman.

Chairman Roth. Thank you, Dr. Young. Let me ask you a rather broad-gauged question. It seems to me that the $64 question is to what extent in the diet industry, if you want to call it that, is weight reduction being regulated? Is it something that ought to be looked upon as a new category? It is my understanding, and I am not an expert in the area of FDA, but it is my understanding that we have created a special category for infant formula.

Dr. Young. Yes.

Chairman Roth. But I guess what I would like to hear from you is to what extent do you think the industry should be regulated, should be treated as a drug or as a food? That makes a major difference. If it is a drug, the regulations are much tougher—preapproval and many other requirements. If it is a food, you do not require that. Or, as I said earlier, should it be treated in a special category? Is this an area where you have adequate authority? Do you have a choice? Can you regulate it as a drug, if you choose? Or are the powers given your agency lacking or deficient, or do you think this is an area where Congress should act?

I recall 10 years ago some regulations were issued, I believe, in your Commission in the area of vitamins.

Dr. YOUNG. That's correct.

Chairman ROTH. And you were finally forced to withdraw those because of the uproar in the Congress. So is this an area where Congress should take action? I would be interested in your comments on this. Let me say, as just one Senator, I feel very strongly—very strongly—that we have a responsibility to ensure that individuals who buy materials in the marketplace, that those materials are safe and sound. But to what extent should we begin regulating? Let me just give this example. Let's assume a product is harmless; it doesn't have any particular beneficial effect, but it does no harm either. Is there any reason that the public at large should not have that choice? Do you care to comment?

Dr. YOUNG. Yes, sir; you have asked excellent questions, and you are right, they are the $64 questions. Let me try to comment in order in the way you asked them, and then if I have forgotten one, please bring it up at the end.

There are three things that you really stress. One is the concept of free choice and how much regulation should exist. The FDA has the authority under the Food and Drug Act to deal with false claims that are made in regards to foods masquerading as drugs, or that whole arena.

You are equally correct that, I believe in section 411 of our law, there was some action by Congress to prohibit FDA from going into the field of vitamins and minerals as food supplements.

I believe that it is very important that the Congress send a clear message to FDA so that we can deal with the type of regulations and law enforcement activities that we discussed today. We are a small agency charged with a great responsibility. FDA has a responsibility for ensuring the safety of 25 cents on every dollar that is spent by each of us in the United States, ranging from food to cosmetics to drugs to medical devices and, therefore, moving to your second point, we have devised our strategy to focus on those issues in food-related problems that we feel are a direct health hazard as our highest priority.

[At this point in the hearing, Senator Gore entered the hearing room.]

Dr. YOUNG. Second, we look at indirect health hazards to determine whether there are things that might influence directly the health of the American public by seducing someone into purchasing something that may not be harmful by itself but by preventing an appropriate medical action by taking a compound which would be less effective.

Third, we deal with economic fraud, but we deal with it in that priority order. We would find it very difficult even to attempt if we thought it was appropriate to regulate the vast array of compounds that may be harmless but not effective.

Now that is not true in drugs. We feel very strongly that the medicines, as you pointed out, must be both safe and effective, and before a drug comes on the market, a new drug application is applied for. But to have a new drug application equivalent for each food that comes on the market would be exceptionally difficult, particularly since many of the data bases with new foods cannot easily be explored in the same detail that it can with drugs. It would be difficult, in my opinion, to broaden the regulatory responsibility of FDA to encompass those foods which are not helpful but also not harmful as well—food supplements.

I would not recommend broadening, therefore, in large measure the regulatory aspects of those nutrients.

Chairman ROTH. If I understand you, what you are really saying is that it is not your recommendation that FDA take over the regulation, either as a drug or special food category, the health industry, per se. Is that a correct statement?

Dr. YOUNG. That is a correct statement, and we would only do that if additional legislative authority or strong recommendations were provided. But I would like to ask counsel to comment on the 411 section in particular because that may be helpful.

Mr. SCARLETT. One of the questions you asked was whether products of the sort that your subcommittee is examining could be regulated as drugs under existing authority. I think it is important to stress that a food product that is offered as a part of a dietary controlled regimen, whose ultimate purpose is to assist people in keeping their weight down or in losing weight, would not be regarded as a drug under our current authority unless the product also made some sort of a therapeutic claim.

The issue of section 411, I think, is an important one. The products that this subcommittee has examined, some of them, at least, are very similar to the types of products that FDA attempted to regulate throughout the 1960's and early 1970's. The agency expended an enormous amount of its resources attempting to impose some order on the marketplace for vitamin/mineral products. We went through a lengthy hearing; it went to court inumerable times in an attempt to defend what it had done. It finally prevailed, substantially prevailed in the second circuit in New York, and at that point after years of work and effort, the agency was about to issue regulations that would have imposed restrictions on vitamin and mineral products and the Proxmire amendment was enacted in 1976 and, in effect, it negated everything the agency had done.

It is my view that products similar to the Herbalife products that are offered for use in weight reduction programs are not different enough from the products that are covered by section 411. Indeed, some of them probably are section 411 products so as to justify the agency in concluding that Congress has indicated that it believes it is not important for the agency to regulate these kinds of products. And I believe if we went after them aggressively, very likely we would end up with an amendment to section 411 that would restrain us with respect to that particular type of activity.

My concern would be that the agency would simply be wasting its time. Unless there is a clear consensus and unless the agency gets clear consistent signals from Congress, I don't think the agency is in a very good position to——

Chairman ROTH [interposing]. Because time is pressing, let me ask you another question. You do agree that you have a responsibility to regulate products that either directly or indirectly are alleged to have therapeutic or medical value; is that correct?

Dr. YOUNG. Absolutely.

Chairman ROTH. Let me ask you this, because the word "indirectly" is, I think, very important. If Company X has no advertisements making such claims, but its distributors consistently make such claims, even though they are independent contractors, is that a basis for finding that the material is being sold as a drug?

Dr. **Young**. You have asked again an appropriate and difficult question. One would have to be able to prove, in my opinion, that the intent was to make these medical claims in order to make that type of case. If there was no intent and another individual was making a claim separately and independently, it might be more difficult to establish such a case.

But I would like to refer that to counsel who is much more equipped to answer the legal questions on it.

Mr. **Scarlett**. Considering the question in the abstract, I would have to first pin down a little bit more precisely what legal action you would have in mind for the agency to take. The agency has three legal tools at its disposal. It can prosecute; it can enjoin; and it can seize. It is possible that actions on the part of persons independent of company X would result in the misbranding of product associated with that person by reason of representations made by that person that have a therapeutic rationale.

In that circumstance, it would be less likely that FDA would consider attempting to impute any motive to bring about that result to company X. If we had evidence that company X was aware of the behavior on the part of its distributors, that would be another question.

Chairman **Roth**. Let me interrupt because time is going fast. Let's assume that the distributors are in a broad-gauged manner making such claims. The manufacturer denies it but either acquiesces or is unable, for whatever reason, to take effective action in preventing the distributors from doing it. Could that be evidence, significant evidence the material is really being sold as a drug?

Mr. **Scarlett**. Failure to act? Being sold as a drug by whom?

Chairman **Roth**. The independent contractors; distributors.

Mr. **Scarlett**. What the independent distributors do must be looked at in isolation. If they make therapeutic claims for a product, either through labeling or orally, that would give the agency a basis for concluding that those products are being promoted as drugs by the independent contractor.

Chairman **Roth**. I think my time is up. I am going to try to keep each of us to 10 minutes on the first round. Senator Rudman was the second person here. So we will follow the early bird rule. Senator Rudman.

Senator **Rudman**. Thank you very much, Mr. Chairman. Gentlemen, I have been listening with interest to your definition of what you believe your responsibilities to be. Let me ask you this. Do you believe that you have under the general enabling statutes that you operate under any responsibility at all in the area of fraud and misrepresentation of products that would indicate they had healthful effects when, in fact, there is no such medical proof, or do you believe that is strictly an FTC matter?

Dr. **Young**. If there is a drug claim made or therapeutic claim made and the products are not healthful, that is under our jurisdiction. If it is merely an advertising claim that describes general effects without dealing with a drug or without dealing with a food supplement, we would be in a more difficult position to establish such action, particularly in view of the section 411 that we cited earlier.

Senator RUDMAN. How your counsel construes 411 and how others might is a matter of reasonable disagreement. But let me ask you this. Did not your office in California, your field office in California, make certain recommendations about Herbalife back in about I believe 1982 or thereabouts?

Dr. YOUNG. Yes; they did. There were some drug claims that were made, some medical claims that were made there and regulatory letters were issued in that regard, and a substantial amount of corrections were made of those claims. They were medical claims at that time and would fall into the category that we would readily regulate.

Senator RUDMAN. So you saw a problem there because the company was doing it. In fact, what the company was doing in its career book, which we discussed yesterday, and in its ads was to make claims on some of these products concerning such debilitating diseases as cancer, diabetes, venereal disease.

Dr. YOUNG. Absolutely.

Senator RUDMAN. Pleurisy, asthma—all sorts of things—burns—all sorts of things, and you found that to be patently false; is that correct?

Dr. YOUNG. That's correct, and we used our regulatory action on those broad health claims and many of those practices ceased.

Senator RUDMAN. And then what happened? And I want to know if you have knowledge of, which I have transcripts of, this company's cable television program and their advertising now says to the public we make no claims. However, they pay for cable time for their program in which they bring people up who give testimonials. I suppose they have a perfect right under free speech to say anything they want to say, and they make parallel claims that you people said the company could not make back in 1982. Are you aware of that?

Dr. YOUNG. Yes, we are aware of it, and we are actively exploring that, sir. That is one of the major problems with dealing with this type of product.

Senator RUDMAN. I would like to ask your counsel a question. Are you familiar with a very substantial body of Federal law which essentially says that even though the company might put out a disclaimer on a particular product, if it encourages, through paid advertising, other people under the first amendment to make those claims that that essentially is the same effect as if they made them themselves? Are you aware of those cases?

Mr. SCARLETT. I have no problem in accepting that legal theory irrespective of whether I have knowledge of the cases. I would like to just make one observation for the record, and that is that the FDA is actively monitoring activities of the nature that you have just described, and I would be very disappointed if this hearing were to bring out activities ongoing in FDA in a way that would compromise our investigation.

Senator RUDMAN. I am not asking you to tell me anything about FDA and what it is doing. I have some knowledge of that. What I am telling you is a matter of public knowledge to anyone who has a television set in this country connected to a cable. That the claims you specifically enjoined, which are obviously fraudulent on their face and being made as an exploitation of the American people, are no longer being made by this company but, in fact, this company has people under the free speech doctrine making these identical claims on television time paid for by them.

Now, I am asking you if you have evidence of that; how long is it going to take you to act? That is my question.

Dr. YOUNG. The action that is required requires very careful documentation and investigation to be sure that we have the type of case that will be sustainable, or we run the very substantial risk of losing the ability to bring forward these types of regulations in the future.

So our investigations must be done very thoroughly, sir.

Senator RUDMAN. I agree with that completely. Let me ask you this without compromising any information. How long has the FDA investigation of this method of promotion of these products, not just this one but others, how long has it been going on?

Dr. YOUNG. FDA has looked at this general indirect type of promotion for a number of years and specifically dealing with weight loss we have intensified our activities in 1½ to 2 years.

Senator RUDMAN. Do you have any particular timetable as to which point you either will decide you will bring action or you will decide you have insufficient evidence to bring action? Is there some timetable you are working on?

Mr. SCARLETT. It is going to be in the relatively near future. Another year.

Senator RUDMAN. So I can make myself perfectly clear because you are looking for feelings from Congress, but I only speak as one person, any company who wants to advertise its product and the product is worthless for weight loss, I tend to agree with what I think the chairman really implicitly said in his question, I suppose the doctrine of caveat emptor only goes so far. I don't think the Government should overregulate and intrude. If the company wants to advertise it's a great product to lose weight, buy it for $10 a pill, there are enough damn fools who want to pay that kind of money, that's their business, but when it crosses the line and starts exploiting the concerns of people about themselves and their children through a variety of very clever means to avoid direct implication and start to essentially exploit people who buy these for more than mere weight loss, I think, sir, that you and your agency have a very serious responsibility, as does the FTC, as does every attorney general's office in this country in the Consumer Protection Division to make sure at least that exploitation doesn't happen.

Dr. YOUNG. You are absolutely correct, and that is why in 1982 we took the action that we did. I can say as a physician that I have seen health-related fraud for years and years, and it is a great problem when you seduce someone from taking appropriate cure to a magic potion that is supposed to do something in a very unusual way, and we feel very strongly about the whole issue of health fraud.

Senator RUDMAN. Let me also say that I do not think that anyone, including probably the original sponsor of 411, ever intended that it should be construed in such a way that fraud, misrepresentation, and exploitation were to somehow be condoned under section 411. Now you didn't say that, but I am just telling you, I do not think that is the intention of that at all.

If these companies want to clean up their act and sell worthless products to the American people, and the American people want to buy them, good luck to them. People throw money away every day on all kinds of foolish things, but they ought not to do it in exploiting the fears of the people in their health in any way. I think that is an absolute vital concern of this committee and this Congress.

Mr. SCARLETT. Senator Rudman, if I can clarify for the record, I did not intend to imply, since I spoke to section 411, that it would immunize the types of practices that you have just described. I was limiting my comments to products promoted strictly for weight control purposes in a relatively above-board fashion.

Senator RUDMAN. I am glad we cleared that up. Let me say, I am heartened to understand you are going to make some decision in the near future. I don't know what that means. Here in Washington it means something different than it means in New Hampshire. The near future will hopefully be something less than 2 years. Thank you, Mr. Chairman.

Chairman ROTH. Thank you. Senator Chiles?

OPENING STATEMENT OF SENATOR CHILES

Senator CHILES. Mr. Chairman, I want to add my appreciation to you for holding these hearings. I understand the subcommittee has heard from experts regarding the use of many diet products, and I am aware of some of the items which are patently fraudulent, such as the miracle pills, creams and tinted sunglasses, plastic earring, rubberized shorts, and similar products.

The weight-loss industry certainly is a multibillion dollar business, but that should not be the focus. Instead, I think the focus should be on whether these products are safe for human consumption and whether they do what the producers say they will do.

Certainly, it is the desire of many people to lose body fat and that means, simply, that weight-loss products have a high appeal. The advertisements which screen consumers from magazines and newspapers or simply come unsolicited through the mail promise easy weight loss with guarantee.

Consumers find the products either don't work or neither does the guarantee.

Is it the role of the Government, though, to tell people what they can or cannot take into their bodies? Is it the role of Government acting in sort of a Big Brother way to regulate every free enterprise which hits the market? Maybe not. I think it is the role of the Government to protect the American people from false claims of products in the free market and the Congress has given broad authority to the Food and Drug Administration to make sure they protect the public from untested sources.

I am glad the food and drug industry is here today. Like many other Senators of the subcommittee, I heard from many people in my State who say their weight loss program works for them. If a product is a food supplement and is advertised only as such and does not lead to serious health complications, then it should be marketed.

However, if it is a drug, then Food and Drug Administration has jurisdiction over marketing of this product.

I would like to know, Commissioner Young, is the FDA currently investigating any of the health industry companies?

Dr. YOUNG. Yes, we are, and primarily we are looking at the claims, new drug claims, to determine whether or not a new drug application needs to be applied for, in view of the claims. That has been our strategy at this current time.

Senator CHILES. As I understand that, then, that would not be just a food supplement, a nutrition supplement. That would be something that actually is a drug—how would you differentiate between them?

Dr. YOUNG. We would differentiate between those two by the following methods:

If the compound in use was designed or promoted to deal with a food nutrition supplement issue and did not make any health claims, we would look at it under the food nutritional supplement components of our agency. However, if that particular compound made the claims, as cited by Senator Rudman, of curing cancer, of curing cirrhosis of the liver, arthritis, baldness—he mentioned just a few of the list of many that were cited by many of these products, and I am not singling out any particular one—we would look at those as drug claims and would use that portion of our statute.

Senator CHILES. And you are then looking—you have current investigations going?

Dr. YOUNG. Yes; and actually, some of the ones that I read in regards to examples of our actions, the CCK, cholecystokinin, was an action just taken recently and also the action in regard to dehydroepiandrosterone is an action we took within the last few months.

So we are continuing to deal with this, and the agency supports a vigorous approach dealing with health fraud and, in fact, developed a health fraud office in the Division of Drugs and Biologics to focus on this.

Senator CHILES. How about the advertisement for APR, arthritis pain reliever, would you consider that a drug claim?

Dr. YOUNG. If it is a medical claim such as arthritis relief, that would be a medical claim and, therefore, would be used as a drug. I am not particularly familiar with that advertisement you have.

Senator CHILES. That happens to be in the pamphlet that Herbalife has. I am just asking you, do you consider that a drug claim or health claim?

Dr. YOUNG. If it is claimed to cure a particular disease, then that would be most usually followed under the drug——

Senator CHILES [interposing]. To be fair, it says, "APR Arthritis Pain Reliever"; bullet, "Temporarily relieves arthritis pain"; bullet, "Soothes"; bullet, "Helps reduce swelling."

Mr. SCARLETT. Sounds like a drug claim to me.

Dr. YOUNG. Surely does.

Senator CHILES. You would consider that a drug claim. Then you would analyze that product to determine whether——

Dr. YOUNG [interposing]. It would be looked at in our investigation, as I responded to Mr. Rudman, and we would consider whether that was a drug claim. We would do the appropriate investigations to determine whether that was and if we found after exploration that it was making a drug claim, we would prioritize the way that we would act on it.

Senator CHILES. Would that have something to do with how a product like that would have to be labeled, what the contents would be?

Dr. YOUNG. If it is a drug, then in order to go on the market today, a new drug application would have to be submitted and it would have to be approved for those medical indications.

Mr. SCARLETT. Senator Chiles, without knowing exactly what is in that product, it is a little difficult for us to respond because for all we know, the product is regarded by Herbalife as a drug, is labeled as a drug, is promoted as a drug and in compliance with the drug provisions of our law. If it has aspirin in it, then it is not doing anything different from Anacin.

Dr. YOUNG. But we would have to investigate it, as counsel mentioned, to determine what the validity of the claims were and what the compounds consisted——

Senator CHILES [interposing]. That is not a food supplement. That is a claim on the basis of a drug so, therefore, it would come——

Dr. YOUNG [interposing]. That would be a medical claim.

Senator CHILES. Can you tell me whether or not Food and Drug is satisfied that Herbalife is only a food supplement?

Dr. YOUNG. There are many products that Herbalife produces and certainly the Slim and Trim 1, 2, 3, and 4 are dealing with dietary supplements and weight-loss regimes. There are a number of other products that we would have to explore to determine whether those are dietary supplements or whether they are making medical claims.

Senator CHILES. You cannot tell me now whether you have done that?

Dr. YOUNG. Well, this is the response we made also to Mr. Rudman's question that we are in the process of looking at these very carefully to determine what our actions should be.

Senator CHILES. Thank you, Mr. Chairman.

Chairman ROTH. Senator Gore.

Senator GORE. Thank you very much, Mr. Chairman. Dr. Young, the FDA first took formal regulatory action in July 1982; is that correct?

Dr. YOUNG. Yes.

Senator GORE. This is when you required Herbalife to take mandrake and poke root——

Dr. YOUNG [interposing]. Yes.

Senator GORE [continuing]. Out of their Formula No. 2 product; is that correct?

Dr. YOUNG. That's correct.

Senator GORE. That claim also cited them for making false claims about the therapeutic capability of some of their products; right?

Dr. YOUNG. Yes.

Senator GORE. Subsequent to this action, you were engaged in what might be described as protracted negotiations with Herbalife; is that correct?

Dr. YOUNG. No; we were looking primarily at our courses of action. I don't think we were under protracted negotiations, to my knowledge.

Senator GORE. Were you trying to get them to stop making false claims on their labels and advertising materials?

Dr. YOUNG. In relation to the initial charge that we brought forward in June 1982, yes. We did follow up work on that. We did not bring additional regulatory actions, other than the 1982 event.

[At this point in the hearing, Senator Chiles withdrew from the hearing room.]

Senator GORE. But you were also conducting an investigation?

Dr. YOUNG. Yes.

Senator GORE. And on September 30, 1983, 15 months after the original notice of adverse findings, the chief compliance officer on the case recommended that some Herbalife products be seized because the officer said they were still making false therapeutic claims; is that correct?

Dr. YOUNG. There was discussion within the agency.

Senator GORE. Specifically that product, and I may have the pronunciation wrong, but I believe it is Tang Kuei; is that correct?

Dr. YOUNG. Yes, it is.

Senator GORE. It was claimed to relieve menstrual disorders and that the product Lifeline was claimed to normalize blood pressure and that the product Cell-U-Loss "breaks up and liquifies fatty tissue." You are all familiar with that?

Dr. YOUNG. Yes.

Senator GORE. Now, isn't it also true that on October 26, 1983, the company's attorney wrote to the compliance officer and noted that Herbalife products were not drugs but were foods and, thus, did not need to be tested prior to marketing?

Dr. YOUNG. There was dialog back and forth on that. We did not come prepared today to have any of our compliance officers here dealing with drugs, but, John, could you comment on that, general information in regard to compliance activity?

Mr. TAYLOR. Yes; we did have discussions, the Los Angeles district had discussions with the individual. One of the things that happened during the period of time you are referring to, we were looking at the possible options. There were a number of decisions to be made.

Senator GORE. Without objection, I would like to ask unanimous consent, Mr. Chairman, to put that letter in the record.

Chairman ROTH. Without objection. This letter and the following letters and memorandums submitted by Senator Gore will be marked Exhibit No. 12.

[Exhibit No. 12 will be retained in the confidential files of the subcommittee.]

Senator GORE. Isn't it also true that on November 28, the same year, 1983, after receiving this letter from Herbalife's law firm, the agency made the suggestion that these products be seized on what was then called "temporary abeyance"?

Mr. TAYLOR. Yes.

Senator Gore. I would like to read from that memo at length and at the appropriate time, I would like to put this in the record also, Mr. Chairman.

Chairman Roth. Could I, because I know the Senator does not want to interfere in any way with the progress of the investigations that are being made, I think if they are going to be put in the record, it should be put under seal.

Senator Gore. That would be fine with me, Mr. Chairman. The FDA has expressed the same concerns to me, and I take it they have expressed them to you, and I do not want to do anything that would hamper their investigation or disclose legal theories or anything of that sort, and I do not think this particular memo would raise that problem. We will do it according to your suggestion just to be on the safe side. But I think this should be part of the record because I think this is a major bureaucratic foulup at FDA and I want to document it rather thoroughly in the record on whatever basis you feel is appropriate in the way that documents are handled.

Let me just say at this point, Mr. Chairman, in view of the vote on the floor, what is your preference? Do you want me to go on for another few minutes, or do you want to break now and come back?

Chairman Roth. I think we will break and come back. The subcommittee is in recess.

[Brief recess.]

[Senators present at the time of recess: Senators Roth, Rudman, and Gore. Senators present at the reconvening of the hearing: Senators Roth, Rudman, and Gore.]

Chairman Roth. The subcommittee will please come to order. Senator Gore.

Senator Gore. Thank you, Mr. Chairman. We just put a memo in the record with some cautionary restrictions. I want to quote from that memo, and I am going to be careful in the quote that I use, I hope.

This is a memorandum dated November 28, 1983. It states:

> We realize that many of Herbalife products are offered with accompanying labeling that make unwarranted therapeutic claims.

So Mr. Apodaca, who wrote the memo, was Acting Director of Compliance for the National Center for Drugs and Biologics, knew or believed there was a problem at that time. However, he goes on to state, taking Herbalife's side to a degree:

> However, the firm's legal counsel has pointed out to you several times that the Herbalife products are clearly foods for special dietary use.

He continues,

> As you are aware, there are several food/drug type products on the market, and we are not prepared to pursue regulatory action through the courts until agency policy covering these products has been established.

He later goes on,

> Therefore, until such time as a joint resolution is reached between the National Center for Drugs and Biologics and the Bureau of Foods on this major issue, we are placing your submission in temporary abeyance rather than disapproving it.

So in November 1983, FDA knew there was a problem and knew that there was a policy obstacle preventing a resolution of the problem; correct?

Dr. YOUNG. Yes.

Senator GORE. I know that the distinction between food and drugs is a tough policy call. Dietary supplements would seem to fall somewhere between a food and a drug, and the enforcement actions that can be taken for each are different. However, this memorandum written 18 months ago lays cut a policy problem that you, Dr. Young, still have not solved. Why has it taken 18 months to address this policy problem?

Dr. YOUNG. Mr. Gore, the policy issue that you spoke to is a difficult one, and there had been discussions between foods and drugs as to which way it would be best to regulate these products. Initially, the regulation was looked at as a food. Most recently we have resolved so that we have the lead responsibility in the Center of Drugs and Biologics. I have been impressed during my brief 10 months of service in Government that even in august bodies as the Senate and House, there are differences of opinion that take time to straighten out, and I would submit that this 18 months is not a long period of time in view of the complexities of the issue we now think we have resolved.

Senator GORE. All you have done is designate one of these two warring offices—war is too strong.

Dr. YOUNG. I think that is too strong.

Senator GORE. I agree. One of these two parts of the agency that are in conflict, you simply have designated one of them as a lead office, but you have not resolved the policy problem, have you? You have not determined yet whether you are dealing with a food or a drug.

Dr. YOUNG. No; that's not true. The question of, as you pointed out, warring is far too strong, even bickering is far too strong. It is a question of how one is going to resolve a very complicated issue and all sides and opinions have to be heard.

We felt after very careful examination of the action that would be appropriate in view of the chilling effect of the 411 rule that we described earlier, that the best way to handle this was to look at the medicinal claim, the drug claim and to move vigorously in that fashion.

Now, it is true that there was discussion over that period of time. I felt that it was a very helpful discussion and a discussion that was required to determine exactly what our policy would be.

Senator GORE. You state that you have made the policy decision.

Dr. YOUNG. The policy decision had been made earlier.

Senator GORE. When?

Dr. YOUNG. And I will submit for the record the exact memorandum sent out by Mr. Hile that describes the——

Senator GORE [interposing]. What is the date on it?

Dr. YOUNG. It should have been in June 1984.

Senator GORE. June 1, 1984. So the policy obstacle, according to your testimony just now, was removed on June 1, 1984.

Dr. YOUNG. That's correct.

[The memorandum referred to follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Memorandum

Date · JUN - 1 1984

From Associate Commissioner
for Regulatory Affairs (HFC-1)

Subject Foods and Cosmetics Promoted with Medical Claims

To Regional Food and Drug Directors
District Directors
Directors, Field Compliance Branches
Center for Drugs and Biologics
Center for Food Safety and Applied Nutrition

In order to implement the recommendations of the vitamin/mineral task force, the agency issued field management directive 131 on January 12, 1983. That document directed the field to submit any regulatory action concerning a human vitamin/mineral product to the Center for Food Safety and Applied Nutrition (formerly the Bureau of Foods), regardless of the proposed charges. It has become apparent during the past year that the recommendations of the task force did not contemplate the type of products we are encountering with increasing frequency.

In an effort to deal with the current situation, the Center for Drugs and Biologics and the Center for Food Safety and Applied Nutrition met with the Director, Enforcement Policy Staff, and the Office of General Counsel on March 7, 1984. It was agreed that food products now being encountered, which are promoted for the treatment of serious disease conditions (without the required proof of safety and effectiveness), shall be considered new drugs. Vitamin/mineral supplements promoted for disease conditions are not exempt from regulatory action by section 411. Accordingly, these products come under the jurisdiction of the Center for Drugs and Biologics.

Therefore, effective immediately, field management directive 131 is cancelled. All recommended regulatory actions against food products represented as foods, dietary supplements, or cosmetics but labeled or otherwise offered for therapeutic claims should be submitted to the Center for Drugs and Biologics. Regulatory action against such products will normally be brought under the drug and/or new drug provisions of the act. A memo concerning our internal review procedures and the agency's views on relabeling, reconditioning, etc., will issue in due course. For the present, the Center for Drugs and Biologics will promptly review and render a decision on all cases presently pending in either center that have been held pending a decision on this matter.

Any turndown by the center will be submitted to the Compliance Policy Council in accordance with the health fraud initiative.

Joseph P. Hile

[At this point in the hearing, Senator Chiles reentered the hearing room.]

Senator GORE. Why has no action——

Dr. YOUNG [interposing]. There has been very definite action. We are in the process of investigating a number of claims that are in place. We have looked at and have followed the——

Senator GORE [interposing]. Well, isn't it still in "temporary abeyance?"

Dr. YOUNG. No; we don't have a temporary abeyance in that at all. We are in the process of exploring the variety of cases and allegations that are made in determining what is the best way to proceed.

Senator GORE. Well, on June 8, 1984, a week after you say this thing was resolved, the district director in charge of the case, with jurisdiction over the case, Abraham Kleks, wrote another memo noting that nothing has been done yet.

Dr. YOUNG. In 7 days.

Senator GORE. Well, no, this is 7 days after——

Dr. YOUNG [interposing]. The policy.

Senator GORE. Yes; after the decision. Now in an undated memo but one which had to be written after June 1, 1984——

Dr. YOUNG [interposing]. It probably is June 8, 1984, from Los Angeles to the——

Senator GORE [interposing]. That is correct. That is the Kleks memo. My memo that is not dated, which is after you claim the policy decision was resolved, however, it is after June 1, and he notes that "it has been 2 years since the agency first took its first action against Herbalife," and states that "on June 1, the Associate Commissioner for Regulatory Affairs stated a policy wherein dietary supplements are supposed to be treated as drugs."

Now, on August 13, 1984, more than 2 months after you claim this thing was resolved, Ms. Grelle, the individual who recommended the seizure to begin with some time earlier, writes a memo and I quote, "Herbalife, again, they won't go away. In fact, the whole situation is getting worse." Still nothing has been done.

On August 12, you did issue a release, a press release in which you stated you had taken action 2 years before and you warned people that you have received reports of adverse effects such as vomiting from people who have eaten the products but still no real action. I am talking about your release here.

[At this point in the hearing, Chairman Roth withdrew from the hearing room.]

Senator GORE. On October 11, 1984, another memo from Ms. Grelle notes that, thus far, agency action has only achieved "the net result was a letter-writing contest with the firms' attorneys and the firm's being more careful about how they misbrand their products."

On November 30, she writes another memo, this time requesting an ad hoc committee be formed to deal with the policy questions whether Herbalife is a food or a drug.

Now, why 6 months after you claim it was resolved is the FDA officer in charge of the case calling for some resolution of the question of whether or not it is a food or a drug?

Dr. YOUNG. I believe the resolution on June 1 dealt with that issue. I also believe, Senator, that in an organization as large as FDA that there will be some disagreement periodically and memorandums of the type that you have described could easily be written.

It is also important to look at the incidence of claims, of problems. And this graph that I am holding up, if you could, indicates the frequency of claims of adverse reactions that we have received over the period of time that we have been looking at Herbalife products.

If you will please note that this begins in 1982, October 1982, and ends in May 1985, and you will note that there is a much larger increase in the claims—and I emphasize claims—of adverse reactions in the latter portion of 1984 and 1985.

Senator GORE. So during all that time you still have the matter in temporary abeyance. It has been 20 months since your staff recommended seizure; 18 months since you put that in temporary abeyance. My question is, what is your definition of "temporary"? Is 18 months temporary?

Dr. YOUNG. We feel that during this 18 months, we have been looking very carefully in determining the type of case as I have described earlier to Mr. Rudman, in regards to the nature of action we should bring forward as an agency.

It takes a substantial period of time to investigate through our compliance officers the exact nature of the case and it is important to emphasize when we go forward with a case, we cannot do so lightly and frivolously and must have a case that is as near ironclad as we can develop.

[At this point in the hearing, Chairman Roth re-entered the hearing room.]

Senator GORE. I certainly agree with that. I think the matter ought to be resolved one way or the other and an 18-month delay is not temporary. I have used up my time, Mr. Chairman. I appreciate it.

Chairman ROTH. Thank you, Senator Gore.

Senator RUDMAN. Mr. Chairman, could we have the chart entered into the record that Senator Gore just discussed with the FDA Director? I would like that included in the record if there is no problem with that.

Senator GORE. The one he held up?

Senator RUDMAN. That is correct.

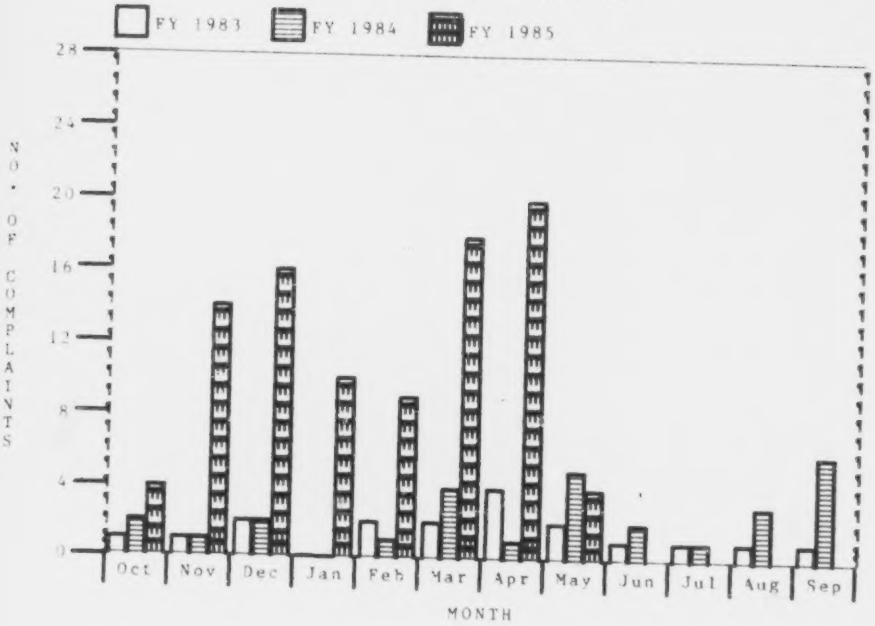
Dr. YOUNG. That is my chart, not Senator Gore's.

Senator RUDMAN. I understand that.

[The chart referred to and two others follow:]

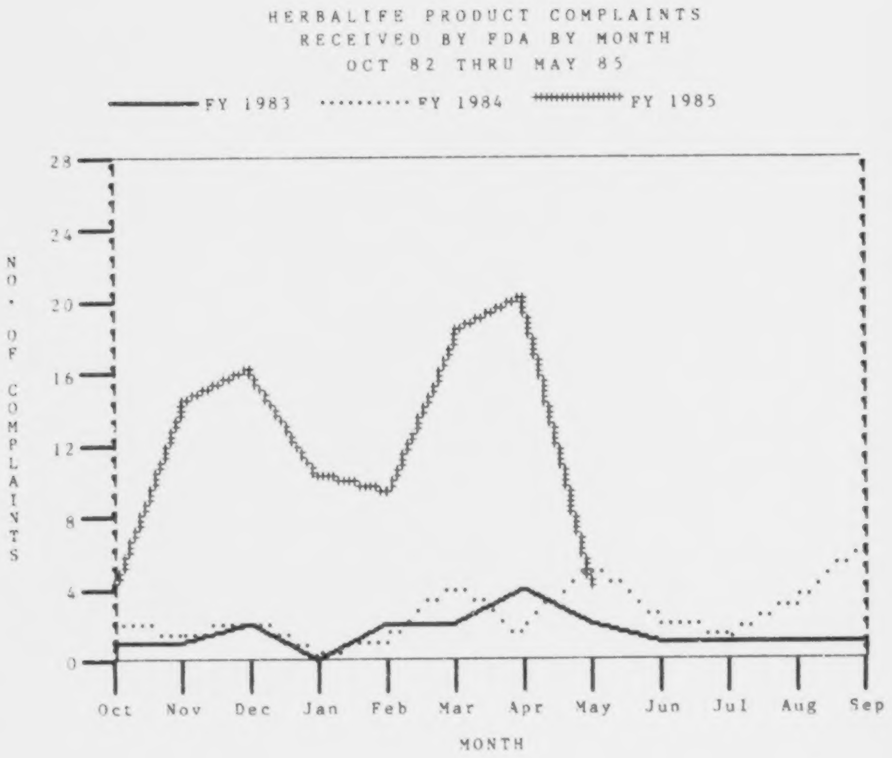
MAY 23 1985

HERBALIFE PRODUCT COMPLAINTS
RECEIVED BY FDA BY MONTH
OCT 82 THRU MAY 85



Prepared by: FDA Office of Regulatory Affairs
Division of Emergency and Epidemiological Operations

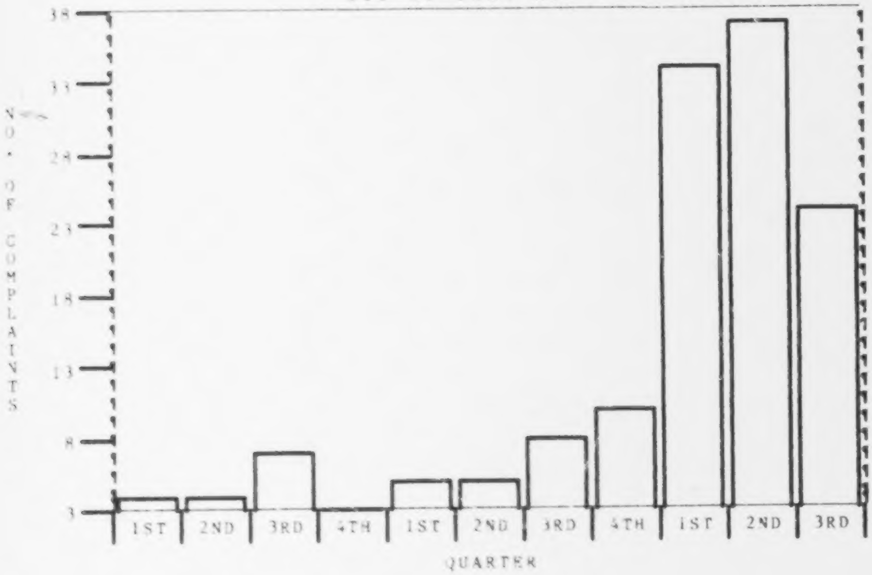
MAY 23 1985



Prepared by: FDA Office of Regulatory Affairs
Division of Emergency and Epidemiological Operations

MAY 23 1985

HERBALIFE PRODUCT COMPLAINTS
RECEIVED BY FDA BY QUARTER
OCT 82 THRU MAY 85



Prepared by FDA's Office of Regulatory Affairs
Division of Emergency and Epidemiological Operations

Chairman Roth. I have a series of additional questions. I would like to carry on just for a moment. I raised the question where distributors were making claims as to whether or not those could be looked upon as evidence that, in fact, the material was being used; there were medical claims being made indirectly.

Subsequently, Senator Rudman asked about testimonials on TV. We have seen a number of cases where products are being sold through the use of anecdotes and testimonials on TV. Can that be used as evidence, in fact, that the material is being sold for medical purposes?

Mr. Scarlett. Yes; if the testimonials relate to claimed therapeutic benefits from the product.

Chairman Roth. Let me ask you a series of questions. Let me read from Herbalife's current official career book, a description of certain products.

In the case of Cell-U-Loss, the official career book says, "It is designed for, one, helping naturally to attack cellulite. Two, aiding in the promotion of circulation. Three, assisting in eliminating excess fluids."

Do you consider this a medical claim?

Dr. Young. That's a pretty gray area in that particular issue. I would like to ask Dr. Forbes, who is a nutritionist and also a physician, to comment.

Dr. Forbes. The products which are promoted for weight reduction purposes are foods for special dietary use. And when it goes beyond that into some of the areas related at least to the ones you just mentioned, those kind of products move closer and closer to being drugs, just as the Commissioner said, so you have a judgment call that has to be made.

I would add that from a medical point of view, cellulite doesn't exist. So it is kind of hard to get rid of something that doesn't exist.

Chairman Roth. Let me ask you another question. Here is the description for Herbal-Aloe. The official career book says, "It's designed to help, one, aid digestion; two, cleanse the system." Is this a medical claim?

Dr. Young. Again, it's a gray area. It is close to a medical claim.

Chairman Roth. It is close. Finally, here is a description of Tang Kuei: "Designed for, one, nutritionally helping irregularity of menstrual function. Two, adding nutrition for the whole body." Is this a medical claim?

Dr. Young. It is close to a medical claim, but it is focused primarily on nutrition and emphasizes one or two aspects of normal bodily function, menses.

Chairman Roth. It is coming close, are you saying, to being a drug?

Dr. Young. Close, but it is very different than saying, as Mr. Rudman did appropriately earlier, it cures cancer, heart disease, arthritis, et cetera.

Chairman Roth. How many reports of deaths were associated with the Cambridge diet?

Dr. Young. There were 12 that were reported and looked at. Mr. Roth, I am a pathologist and I have in my experience of practice supervised and conducted in excess of 2,000 autopsies. In looking at an autopsy case or medical case, it is extraordinarily important to do three things:

First, the autopsy must be carefully conducted, and I have reviewed many of the reports, not so much on the Cambridge diet but I have with me the records of those autopsies and clinical cases that were submitted as portions that might be related to Herbalife. So that examination must be done very accurately.

The second is that one must do a cause-and-effect analysis to be able to be sure that the particular case resulted from a particular event that could be identified. In my practice of individuals, approximately 3 to 5 percent of total deaths that I have seen, we could not find a lesion that was incompatible with life. Therefore, one must look at the total population to determine a cause-and-effect relationship.

Finally, it is necessary to normalize the number of deaths that occurred on that particular diet and compare that to similar symptoms in a population of a comparable age. In the case of the Cambridge diet, it was difficult to do this. However, when CDC went through this exercise for the liquid protein diet, they were able to find in a study that I have with me, and I will be delighted to submit it for the record, increased mortality associated with the liquid protein diets. Twelve cases that were associated more directly with the Cambridge diet plans are more difficult to quantify.

There is one that seemed to be more suspicious than others, but I do have the summary and some of the cases with me, and I will be glad to address them, if you wish.

Chairman ROTH. You say there were how many in the case of Cambridge?

Dr. YOUNG. In the case of Cambridge, there were 12 deaths.

Chairman ROTH. How many in the case of Herbalife?

Dr. YOUNG. Herbalife, there are alleged to be five deaths that could be related, and I must emphasize that these are deaths alleged to be associated with the use of the products.

Chairman ROTH. Would you submit for the record the identification of those five alleged cases? This submission and the study submitted by Dr. Young will be marked exhibit No. 13.

[Exhibit No. 13 may be found in the files of the subcommittee.]

Chairman ROTH. What is the current status of your investigation in these deaths?

Dr. YOUNG. We have reviewed the documents, and I have these with me. Of the particular cases, it is very difficult to establish in any of the five cases an absolute correlation between the death and the product that was consumed. There are inferences that there may be some association with rapid weight loss, but there is nothing that, in my opinion, absolutely establishes these as cause-and-effect related.

Chairman ROTH. My time is up. Senator Rudman?

Senator RUDMAN. Mr. Scarlett, I just have one question, kind of a curiosity, I guess you would say. How long have you been general counsel of FDA?

Mr. SCARLETT. About 4 years.

Senator RUDMAN. Were you with the agency before that as well?

Mr. SCARLETT. Yes, I was.

Senator **Rudman**. Do you know the gentleman who is sitting over your right shoulder? I don't know his name. I assume he is an associate of Mr. Hughes in some way.

Mr. **Scarlett**. They introduced themselves to me during the break, but I had not met them before.

Senator **Rudman**. Because during the questioning by Senator Chiles, I observed something I thought was a little unusual. I thought maybe the gentleman worked for you, but I was advised he didn't. He passed you a note after Senator Chiles asked you a question. I believe he is a lawyer for Mr. Hughes. That is his privilege. It is a free country. Is there anything personal about the contents of that note?

Mr. **Scarlett**. No, "It has a drug number." All he was trying to tell me, I gather, from the cryptic note was that the product Senator Chiles was discussing was regarded by them, apparently, as a drug.

Senator **Rudman**. I just make a general observation. He was within his rights to do it. I think it is a little unusual when counsel for someone who is before this committee decides to help a Government witness in answering a question. I think it is very charitable. I am not sure it is appropriate. As I said, there is probably nothing wrong with it.

Mr. **Scarlett**. He handed it to me over my shoulder.

Senator **Rudman**. Obviously, he passed you a note. I assume you had to look at it. Maybe it said there was a rip in your suit. [Laughter.] Thank you.

Chairman **Roth**. Senator Gore.

Senator **Gore**. No question.

Chairman **Roth**. Senator Chiles?

Senator **Chiles**. Nothing further, Mr. Chairman.

Chairman **Roth**. Mr. Rinzel has a few additional questions he wants to ask.

[At this point in the hearing, Senator Rudman withdrew from the hearing room.]

Mr. **Rinzel**. I want to ask you about some of the items that are contained in Herbalife products. Is comfrey approved for human use? Our experts told us that comfrey has been shown to induce malignant tumors in rats. Can you say whether the comfrey contained in Herbal-Aloe distributed by Herbalife is safe for human consumption?

Dr. **Young**. I would like to defer that question, Mr. Rinzel, to Dr. Forbes and John Taylor.

Mr. **Taylor**. As far as the comfrey is concerned, we list it as undefined safety. However, at levels that purport to be in the product, our experts have cited that it wouldn't be a major problem.

Mr. **Rinzel**. It would not be a major——

Mr. **Taylor** [interposing]. It would not be a problem at the level that is found in the product.

Mr. **Rinzel**. What is the law about chemicals that induce tumors?

Mr. **Taylor**. Well, we don't have any—I don't know where they got their scientific data, but we have no study to show that it has produced malignant tumors in animals.

Mr. RINZEL. Do you plan to get in touch with Dr. Tyler who reported that information to us?

Mr. TAYLOR. Yes, we will.

Mr. RINZEL. What about chaparral? We were advised that chaparral is principally made of NDGA or contained NDGA and this has been shown to cause cysts and kidney damage in rats. It was removed from the GRAS list in 1968—generally recognized as safe list. Is that your understanding or what is your understanding?

Mr. TAYLOR. That we will also have to check. I am not familiar with the studies nor the experts you talked to familiar with the studies.

Mr. RINZEL. Do you intend to get in touch with Dr. Tyler? He is supposedly one of the Nation's experts on herbs and has written some books.

Is it legal in the United States to sell kava-kava as a food?

Mr. TAYLOR. No, it is not.

Mr. RINZEL. It is not legal?

Mr. TAYLOR. No.

Mr. RINZEL. Are you aware of Herbalife products that contain kava-kava?

Mr. TAYLOR. I realize one of them does contain kava-kava.

Mr. RINZEL. What has the agency done about that?

Mr. TAYLOR. Until this time, nothing.

Mr. RINZEL. What about Schizandra berries, Schizandra plus; are you aware of the ingredients in that product?

Mr. TAYLOR. Yes, I am.

Mr. RINZEL. And is it legal to sell those ingredients as a food supplement in the United States?

Mr. TAYLOR. Let me explain what we did as far as the herbs were concerned. We had each of these products reviewed by the experts to look at the safety issue. This is at the beginning of when we first started to look into the products. We found two of the herbs which we knew that caused a distinct product——

Mr. RINZEL [interposing]. Mandrake and——

Mr. TAYLOR [interposing]. Yes.

Mr. RINZEL. You asked them to take it out and they took it out?

Mr. TAYLOR. That's correct.

Mr. RINZEL. Did you do anything to recover the materials, bottles that had already been sold containing those products?

Mr. TAYLOR. No, we did not.

Mr. RINZEL. Why was that?

Mr. TAYLOR. Because we felt the level that was present in these products did not warrant the manpower to remove them from the market.

Mr. RINZEL. Did not warrant the manpower?

Mr. TAYLOR. To remove them from the market. Although they are not supposed to be there, we did not feel they presented any major hazards, so they were not removed from the market.

Mr. RINZEL. A minor hazard. What manpower would FDA have to extend——

Mr. TAYLOR [interposing]. If the product had been recalled from the market, we would have had to check to see if they were actually removed, we would have to monitor the recall, et cetera. So a policy decision was made.

Mr. RINZEL. In the notice of adverse findings that the FDA sent to Herbalife, Cell-U-Loss was alleged to be misbranded because it claimed to increase circulation; NRG was misbranded because it falsely claimed to aid mental alertness.

The subcommittee has reviewed current copies of Herbalife's official career book. Cell-U-Loss is touted as "aiding in the circulation." NRG is touted as "designed to aid mental alertness." Has the FDA changed its mind as to whether or not those items are misbranded?

Mr. SCARLETT. Those are the very things we are reviewing now. I do request, with all due respect, that we not be asked to provide specific answers.

Chairman ROTH. We are leaving the record open. There may be a number of further questions that we would like to have answered in writing. Thank you, gentlemen, very much.

[Dr. Young's prepared statement follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

FRANK E. YOUNG, M.D., Ph.D.

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

COMMITTEE ON GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

MAY 15, 1985

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

Thank you for the opportunity to meet with you and the members of the Subcommittee today to discuss dieting and the Food and Drug Administration's (FDA) activities concerning the regulation of products promoted for weight loss.

DIETING

It has been postulated that as many as a third or more of adult Americans are overweight. Although there is no hard and fast definition of what "overweight" really is, it is clear that for most people extra pounds present a clear and present danger to their health. Convincing evidence from the National Institutes of Health's Framingham Study, the American Cancer Society Study, insurance companies and others indicates that life expectancy is better for those who are not overweight and decreases as the pounds are added on. People with diabetes or high blood pressure suffer more complications if they are overweight and benefit from losing weight. Massively obese people experience ill health in many ways as a result of their extra fat tissue. For these reasons, as well as for cosmetic ones, millions of Americans diet.

It is estimated that at any given time, more than 20 million Americans are on a diet. Some try to starve it off, melt it off, and sometimes even sleep it off. Yet in spite of all this dieting, Americans on the average are gaining weight. Even for those successful dieters, fewer than 20 percent are able to keep off the pounds they shed. So what does it take to lose weight? The answer lies not in complicated hocus-pocus, but in a few easily understood scientific principles.

The most basic of these principles is that the body needs a certain amount of energy, expressed as calories, to maintain its weight. To lose weight, you have to use up more calories than you take in through food. To gain a pound of fat, you must eat about 3,500 more Calories than you use up. What kind of food the calories come from makes little difference.

But counting calories is, admittedly, difficult. And, although calorie counting alone can be useful for helping one to lose weight, permanent weight reduction usually requires some sort of behavior modification as well. For example, you can learn to pick your foods to get the maximum nutritional value for the minimum number of calories.

Another good idea for most people is exercise. Regular physical activity does help to use up calories. Some studies show that appetite may be better regulated in people who are physically active and that exercise may change metabolism in a way that favors weight loss. Exercise also can contribute to good health in general.

FDA'S REGULATION OF WEIGHT LOSS PRODUCTS

FDA does not approve or regulate weight loss programs or diets except when a product is involved. Under the provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act) we have authority over those food, drug and medical device PRODUCTS that are specifically promoted for or make claims about weight loss.

Over the years, FDA has published regulations and proposals regarding "foods for special dietary use" which are promoted to meet some of the dietary needs of persons who are dieting. As a prime example, one regulation provides definitions of and label statements for low calorie and reduced calorie foods. In the preamble of the rule, the Agency recognized the importance of a total dietary program for weight reduction and weight control in which adequate amounts and balances of nutrients are provided and total calories are controlled.

As an extension of the rule on low and reduced calorie foods, FDA published a proposal last year to amend the food labeling regulations to provide for the exclusion of nondigestible dietary fiber when determining the calorie content of a food for nutrition labeling purposes. This proposal will allow for a more accurate declaration of the available calories in a high-fiber food.

In addition, on August 6, 1984, a regulation went into effect that requires manufacturers of certain protein products promoted for weight reduction to provide a warning statement to alert consumers of potential hazards of using the products when more than 50 percent of the product's calories come from protein. This rule was an outgrowth of an FDA investigation in the late 1970's into several deaths linked to the use of liquid protein diets containing less than 400 Calories a day.

In addition to food products that can be helpful in a weight loss program, there are some drugs that are promoted for use in helping the dieter. Two such products are phenylpropanolamine, or PPA, and benzocaine. PPA is available to the public in a number of prescription and over-the-counter (OTC) medications including appetite suppressants. Benzocaine is an ingredient in many OTC diet gums and candies. It acts to numb the tongue and reduce the sense of taste. The use of these ingredients in OTC drugs has been the subject of review under the Agency's ongoing OTC Drug Review--a program designed to assure the safety and effectiveness of all OTC drugs on the market.

But the important concept the dieter must grasp is that there is no magic potion or pill that will enable one to consume a high calorie diet while at the same time lose weight and keep it off. And although dieters are easily tempted away from regimens of counting calories by a vast array of articles, books, pills, potions and devices that promise to get the excess pounds off quickly and effortlessly, it takes a good deal of time and effort for a diet to be successful.

True, some diets and diet products can result in a quick weight loss, but they rarely have any permanent effect without appropriate behavior modification. During the first week to ten days, the weight loss from very low calorie diets is predominately from water and protein rather than body fat. Such dieters often enter into a cycle of quick weight loss followed by weight gain when normal eating is resumed, and find it even more difficult to lose weight when the next diet is attempted.

One type of diet that was promoted for such quick and easy weight loss was the very low calorie/high protein diet. In the 1970's, this diet was advertised as a panacea for the overweight, with promises that they could "burn fat off" more quickly than with a regular balanced diet. As with many "crash" diets, not only was the quick weight loss that the dieter experienced on these low calorie/high protein regimens temporary, but also dangerous. In addition to a loss of body fat, such an uncontrolled weight loss program can lead to an excessive loss of body fluid or dehydration, electrolyte imbalance, and loss of lean body mass. Also, no foods have the ability to "burn fat off." Body fat is "burned" or gotten rid of only by using more calories or energy than is supplied by the food you eat. A claim that a food can "burn fat off" is fraudulent.

As I mentioned earlier, millions of Americans are on a diet at any given time. Today, although many individuals are dieting in a responsible manner, it is also true that more people are shopping for specialty foods, joining spas and aerobic exercise classes, and trying to maintain or get back that svelte and youthful look. This health consciousness includes a concern about diet, but in the quest for this "new look," many are easily duped by the promises of fraudulent weight loss claims.

Sometimes the claims made about weight loss devices can border on the ridiculous--for instance appetite-suppressing eyeglasses with colored lenses that are supposed to project an image to the retina that dampens the desire to eat.

Another recently promoted device, the electrical muscle stimulator, has legitimate medical uses in physical therapy but is worthless for weight loss or figure firming. Claims that stimulation from these devices has the figure-toning ability of 3,000 sit-ups, for example, are without any scientific basis. Further, these devices are often promoted for home use through mail-order sales and can be dangerous if not handled correctly. There have been reports of electrical shocks and burns, and the devices can be particularly hazardous to pregnant women and to people with heart problems, pacemakers or epilepsy.

A wide assortment of wraps and garments, some with accompanying lotions to be rubbed on the body before donning the apparel, have been promoted as ways to "burn fat." But facts show that its the consumers that get "burned" and only their wallets that get thinner. The creams, gels, wraps, belts and sweatsuits reduce body dimensions by removing fluids--that is, the user sweats it off. Again, this is a very temporary loss and can, in some cases, cause severe dehydration and chemical imbalance.

EXAMPLES OF FDA ACTIONS AGAINST WEIGHT LOSS PRODUCTS

FDA has taken legal action against several promoters of weight loss products for making unsubstantiated claims. For example, starch blockers (tablets prepared from raw beans and other ingredients) are products that have been advertised and sold nationwide with claims that they block or impede starch digestion to help in weight control and weight reduction. Medical claims that these pills block the absorption of carbohydrates and nullify calories from starchy food have never been substantiated by the submission of data and thus they have been declared new drugs and declared illegal by several Federal courts because they are unapproved new drugs. FDA has seized these products after promoters failed to comply with our request to cease sales.

Another unapproved drug promoted for weight loss and against which FDA has taken regulatory action is DHEA. Touted as a "natural" weight loss product, DHEA, known chemically as de-hydro-epi-androsterone or de-hydro-androsterone, is a steroidal hormone and can be derived from human urine and other sources. FDA has not received any data to substantiate claims made for DHEA, and it is not known what the effect might be of reintroducing into the body a concentrated amount of this hormonal breakdown product that people normally excrete.

FDA also has initiated regulatory action against manufacturers and distributors of an alleged weight-loss product containing the hormone CCK or cholecystokinin. CCK, a hormone involved in human digestion, has been sold both by mail and through retail stores with claims that it can decrease hunger and can cause sudden and dramatic weight loss. In the absence of any information supporting these claims or of the safety of CCK, FDA has told firms that manufacture or distribute these products to discontinue marketing.

Other products that FDA regulates as drugs and that have been promoted for use in treating obesity or stimulating weight loss include human chorionic gonadotropin (HCG), arginine and ornithine. Both FDA and the American Medical Association have stated that HCG, a hormone extracted from the urine of pregnant women, is useless for weight loss. Approved for treating certain reproduction problems, FDA requires all labeling and advertising for HCG to state that it has not been shown to be safe and effective for weight control.

Arginine and ornithine are amino acids. Manufacturers have claimed that pills made of these amino acids stimulate human growth hormone, causing the user to "burn fat" overnight. No data have been submitted to FDA to support this claim. Some very preliminary studies show that these amino acids have been shown to stimulate human growth hormone when administered intravenously. It is unlikely that small amounts of these amino acids taken orally would stimulate the production of growth hormone and there are no data to show that increases in human growth hormone would cause a person to lose weight. If these pills do what the manufacturers claim, they could in fact be dangerous because in the process they also could stimulate other hormones, altering insulin levels and carbohydrate metabolism.

Glucomannan is another product promoted for weight loss. Extracted from the konjac root, it is a food used in Japan and other Eastern countries. Promoters claim that the powder, taken in capsule form before meals, absorbs liquids and swells in the stomach to form a gel and reduce hunger. FDA reviewed glucomannan in 1982 and is of the opinion that there are insufficient scientific data available to support its use as a substance Generally Recognized As Safe (GRAS). Under the 1958 Food Additive Amendments, any substance intended for use as a component of food has to be either GRAS, prior sanctioned or permitted under a food additive regulation. FDA has informed the manufacturers of glucomannan that to market this product they must supply evidence that the substance could be listed as GRAS or to support a food additive regulation.

Another food product that has been promoted for weight loss is spirulina, a dark green powder or pill derived from algae. It can be legally marketed as a food if it is correctly labeled and not contaminated or adulterated. Claims that spirulina acts on the brain's appetite center to switch off hunger pains, however, are drug claims and there is no evidence demonstrating spirulina's safety and effectiveness as a diet product.

This example of a food product for which certain claims may be made that cause it to be a drug is not a unique one and brings us to the heart of the problem with respect to the regulation of many weight loss products. Some products promoted for use in weight loss programs have legitimate food or drug uses but are misrepresented by their promoters or in diet books and plans. Such is the case many times with vitamin/mineral and herbal products.

Vitamins and minerals are chemicals needed only in small amounts in the diet for normal growth and life. Consumption of these chemicals may be substantially reduced when food intake is restricted to lower calorie intake. Under these circumstances, a vitamin and mineral supplement that provides about 100 percent of the recommended allowances for such nutrients may be appropriate. Frequently, however, supplements containing grossly excessive amounts of nutrients are promoted along with a diet plan that is designed to lower the buyer's total caloric intake.

This type of misrepresentation also occurs with herbs. Although very useful in producing many important pharmaceuticals, in adding variety, color and taste to many of our food dishes, and in giving us some unique teas, herbs are not always safe and nutritious.

Some manufacturers and distributors are promoting herbal mixtures for a variety of weight control programs. The diet plans may replace one or more meals a day with low calorie product mixtures including herbs, vitamins and minerals, lecithin, senna leaves, kelp, chickweed, and dandelion, but no significant data has been provided to demonstrate that such ingredients do anything to control weight gain or ensure weight loss. Such products are unnecessary since its the eliminations of meals, i.e., lowering the daily intake of calories is what causes the weight loss.

In addition to not being the magic answer to weight loss, herbs can be unsafe. No one would knowingly consume poisonous herbs, of course. And no responsible herb company would even consider putting such herbs in its products. But the fact is that poisonous herbs have been found in diet aids in low levels and FDA has taken action against products in such cases. And although we know about the toxicity of some herbs we do not know enough about many to conclude that they are safe as currently promoted in some weight reduction plans.

REGULATORY STRATEGY

In the weight loss product area, especially those products that are vitamin/mineral supplements, herbal mixtures or other such foods, it is often difficult to draw a clear line between legitimate products and fraudulent ones. Advertising claims can be made by word of mouth instead of in print or on labels. Business names and addresses can be changed. Some operators move out of the country and deal through the mails.

Faced with these problems, FDA has attempted, over time, to modify its strategy to make the most effective use of resources for dealing with those products which represent a health fraud. Until the 1960's, the most common tool used was prosecution. A number of cases were successfully tried and these achieved some deterrent effect. But because this is a more time-consuming and resource intensive approach to the problem, the Agency has expanded its enforcement program to include the use of other judicial and administrative measures such as seizures, injuctions and regulatory letters.

As part of its enforcement program, which includes routine inspections, FDA also investigates individual complaints, obtains information and collects evidence regarding potential violations of the FDC Act. Decisions as to the significance of the findings obtained from an investigation and what action should result are made in accordance with established compliance policy that reflects factors such as health hazard potential, extent of product distribution, nature of the misbranding, jurisdiction of other agencies, and available resources. Whenever possible, FDA also coordinates its investigations and enforcement strategies with other agencies such as the U.S. Postal Service, Federal Trade Commission, and State officials.

Finally, I believe that public education is probably the most effective and cost efficient way of combating health fraud, especially economic fraud. This is because the surest way to reduce health fraud is to reduce consumer demands for the fraudulent products. In the weight loss product area, FDA has begun a public awareness campaign that includes a slide show, exhibit and video tape focusing on diet books, low calorie diets, body wraps, starch blockers, and other weight loss products and urges consumers to consult their physicians prior to beginning diets and to be aware of the general principles which apply to reduction diets. This is the message we need to get to consumers. There is no easy method or magic food, drug, or device to melt away fat.

CONCLUSION

So what does it take to lose weight? The answer does not involve miracles or new discoveries. To lose weight, a person must use more calories than are taken in. This can be done either by eating less or by exercising more, and most experts recommend a combination of the two. Some authorities believe that exercise can even decrease the appetite, in addition to helping to use up calories at a higher rate for some time following the exercise period. Also, many people find that when they exercise they feel better, not an unimportant advantage to the dieter.

Before embarking on any weight-loss program, would-be dieters should consult their physicians to be sure there are no underlying medical problems and that the diet and exercise program they are contemplating is right for them. Talking to a registered dietitian or qualified nutritionist also can be helpful in planning a well-balanced weight loss program.

When it comes to weight loss, the following basic principles apply:

-- Consult a physician and, if possible, a dietitian before embarking on any very restricted diet.

-- Aim for a moderate weight loss of one to two pounds a week.

-- Reduce portion sizes but maintain a balanced diet from the four basic food groups: grains and cereals; dairy products; fruits and vegetables; and meat, poultry and fish.

-- Limit intake of alcohol, fats, sweets, and high-calorie foods.

-- Exercise regularly--increase exercise if possible.

As for weight maintenance, once the pounds are shed, many experts recommend that dieters become aware of the eating habits that made them gain weight in the first place so that they will not return to them. One way to keep weight down is to stay with the same foods that were eaten during the diet. After weight loss, some people find it useful to continue counting calories to make sure they are not starting to overeat again. Any exercise program undertaken while dieting should be continued as part of life's daily routine. A lasting weight loss does not happen overnight; and maintaining reasonable weight is a lifetime endeavor.

This concludes my statement. I will be pleased to answer any questions you or your colleagues may have.

Chairman ROTH. Next we would call forward Vaughn Feather, the president of Cambridge International, and Robert Nesheim. Gentlemen, will you raise your right hand?

Do you swear the testimony you will give before this subcommittee will be the truth, the whole truth and nothing but the truth, so help you God?

Mr. FEATHER. I do.

Mr. NESHEIM. I do.

Mr. BANKER. I do.

Chairman ROTH. Please be seated. It is already 11:30, so we would appreciate your summarizing your statement so that we can proceed as quickly as possible with any questions.

TESTIMONY OF VAUGHN FEATHER, PRESIDENT, CAMBRIDGE PLAN INTERNATIONAL, ACCOMPANIED BY ROBERT O. NESHEIM, SENIOR VICE PRESIDENT, SCIENCE AND TECHNOLOGY, CAMBRIDGE PLAN INTERNATIONAL, AND JOHN BANKER, ESQ.

Mr. FEATHER. Thank you, Senator. I have supplied to staff counsel a full statement, and I will attempt to be as brief as possible and read a shorter version of the statement.

My name is Vaughn Feather. I am the president of Cambridge Plan International. Since 1980, Cambridge Plan International has distributed in this country a very low calorie dietary formulation know as the Cambridge Diet, as part of a program for persons seeking seriously to lose weight. With me today is Robert O. Nesheim, Ph.D., our company's senior vice president for science and technology. I have a copy of Dr. Nesheim's statement for the record.

From our standpoint, this investigation is a welcome one. We believe that a balanced and nutritionally fortified very low calorie diet such as ours, when offered as part of a well-considered support system, offers genuine promise in the area of weight reduction.

Since 1982, when publicity concerning the Cambridge Diet was at its peak, our products and programs have undergone major changes. We welcome the investigation for the opportunity it gives us to explain those changes.

We believe there is a need and a place for responsible commercial weight reduction programs and products which are administered with the cooperation and assistance of physicians. In the

Cambridge Plan as it presently exists—after 5 years of experience and with important changes from its early days—we think we may have such a program.

The Cambridge Diet with which we started was a very low calorie formulation conceived in the early 1970's by Alan Howard, Ph.D., of Cambridge University. During the 1970's, it was tested at various European research centers, in addition to Cambridge. I have for the record a list of published research on this and other very low calorie diets.

Chairman ROTH. This submission and other submissions by Mr. Feather will be marked exhibit No. 14.

[Exhibit No. 14 may be found in the files of the subcommittee.]

Mr. FEATHER. The original Cambridge Diet was comprised of a natural food base—nonfat dry milk and soy flour—enriched with 100 percent of the USRDA of vitamins and minerals, with trace elements and electrolytes, to create a nutritionally dense formulation providing 330 calories per day. It was originally marketed by Cambridge Plan to be used as an exclusive source of nutrition for periods of up to 4 weeks, a period based on the views of the European researchers concerning unsupervised use of the diet.

I believe one of the two key questions to be asked of any diet or weight-loss program is whether it is effective. That does not mean whether it produces quick or immediate weight loss—most diets, good and bad, do that—the test is whether the weight loss is enduring. Very few diet programs pass the test.

There is, however, evidence that the Cambridge Diet Program can provide enduring weight loss. In 1982, we identified over 800 persons who had lost 50 pounds or more on the Cambridge Diet. For the next 2 years, the Opinion Research Corp., of Princeton, NJ, conducted annual telephone surveys of those persons. We think the results of their survey are surprising.

Two-year data are available on 354 of these persons. This group originally weighed an average of 250 pounds. Their original mean weight loss was 60.8 pounds. After 1 year they had maintained on the average all of that weight loss. After 2 years, 42 percent had maintained their entire original weight loss, or had lost more weight. As a whole, the group had maintained on the average over 48 of the original 60 pounds of weight loss.

The other key question is, of course, safety. When we introduced the Cambridge Diet in this country, we relied upon the results of the European clinical tests, which supported its safety, and on the fact that the European physicians and scientists who conducted those tests had concluded that the diet was safe for unsupervised use for periods of 6 weeks.

Since then, we have also tried to evaluate the experience of consumers of the Cambridge Diet. To secure reliable evidence of usage, we commissioned Prof. James Carman, the acting dean of the graduate school of business of the University of California at Berkeley, to conduct a projectable survey to determine how many persons had used the diet in this country during 1981–82.

Professor Carman's survey, which was concluded in November 1982, determined that during a 21-month period, approximately 5 million Americans used the diet. Carman's survey was published as part of a book. I have for the record a copy of that report.

In contrast to the 5 million users of the Cambridge Diet during this 21-month period, our company has received—over the entire 5 years we have been in business—about 200 complaints of consumer injury. One hundred and sixty of these, or about 80 percent, relate to salmonella found in an ingredient sold to us by a supplier in mid-1982. This resulted in a voluntary product recall.

The rest of the complaints over this 5-year period—40 in all—relate predominantly to problems of a transient nature attributed by consumers, rightly or wrongly, to use of the diet.

[At this point in the hearing, Senator Chiles withdrew from the hearing room.]

Mr. FEATHER. For the past 2 years, we have received no complaints at all.

As we have informed the subcommittee's counsel, we have received five serious complaints asserting that the diet caused deaths. Three of these resulted in lawsuits, and two have not been pursued. Of the three, one was not on our weight-loss program, and the other two shared no common pattern. In the one case where complete medical records exist, the records have been reviewed by four independent medical experts, including some of the leading U.S. authorities on very low calorie diets, and each of them concluded that the death was not caused by the diet.

I believe FDA has investigated these and similar reports. As I understand it, FDA does not contend that the evidence shows that the Cambridge Diet was a cause of any of the incidents it has investigated, although it has also been unwilling to exonerate the diet.

It is appropriate to ask why the diet——

Chairman ROTH [interposing]. Let me interrupt. Were any of those cases settled with a payment of any funds to the claimant?

Mr. FEATHER. There was one case that was settled.

Chairman ROTH. How much money was paid?

Mr. FEATHER. If you would like me to ask, I will. As part of the settlement, we agreed both sides would keep that matter confidential. Senator, obviously, if you would like me to give you that amount, I will.

Chairman ROTH. Just give me an approximation.

Mr. FEATHER. It was a low six-figure settlement, and I would be happy to provide that information to the staff.

Mr. RINZEL. That has been in the newspapers, hasn't it, that same number?

Mr. FEATHER. Yes.

Chairman ROTH. Proceed.

Mr. FEATHER. It is appropriate to ask why the diet has been linked to these incidents. I think the answer lies in a combination of factors. First, the Cambridge Diet was introduced in this country shortly after the 1978 experience with liquid protein, which was a very different and dangerous diet. Liquid protein and the havoc that it caused left an understandable aftermath of concern and uncertainty.

Indeed, during our early years, it was not uncommon for the media and some medical authorities to refer to the Cambridge Diet as a "liquid protein" diet, and to be unwilling or unable to distinguish these two very different diets.

Second, the safety of the Cambridge Diet received a great deal of highly publicized criticism in the press and on television based on the conventional view that there is something risky about any diet of less than 800 calories per day. As a matter of fact, in the press alone the diet received over 63 mentions in press coverage.

At that time, the Cambridge Diet was also being used by what I believe was an unprecedented number of people. I believe that these matters frightened users of the diet; I think they created a climate of alarm in which consumers were influenced to link to their use of the diet ailments and medical problems which would have occurred even if they had not been dieting.

Again, over a 5-year period and out of more than 5 million users, we have received only 40 complaints.

Now I would like to briefly discuss our response to the criticism of the Cambridge Diet.

While we have not agreed with it, we have tried to adapt to the medical criticism of the Cambridge Diet. The basic criticism was that the diet was so low in calories as to be unsafe unless taken under medical supervision. Professor Carman's survey had disclosed, however, that over 80 percent of our customers were not adhering to the criticized 330 calorie per day program, but were nevertheless achieving acceptable weight loss. Despite our belief in the diet's safety, we eventually concluded that we could modify our 330-calorie program to avoid the criticism without significantly lessening its effectiveness. We, therefore, changed our programs in ways that I will describe later.

During this same period, we sought to establish a better relationship with the Food and Drug Administration. In late 1982, I requested a meeting with Dr. Sanford Miller, Director of the then Bureau of Foods, to discuss our operations and products. At that meeting, Dr. Miller made three basic suggestions, which we tried to follow.

First, Dr. Miller suggested that because the Cambridge Diet was sold for use as an exclusive source of nutrition, we adopt the quality assurance standards then proposed for the manufacture of baby foods, despite the fact that the baby food regulations did not apply to our products. We followed that suggestion. Since early 1983, the quality assurance procedures used in the manufacture of our Cambridge Diet products have been based on those guidelines.

Second, Dr. Miller suggested that we establish a dialog with our critics—solicit their views, explain our position, present our evidence, and so forth. To this end, Cambridge Plan funded in June 1983 a symposium on very low calorie diets. It was organized by Drs. George Blackburn and Fred Stare of Harvard University and Dr. George Bray of the University of Southern California. Thirty participants from five countries attended and addressed scientific and clinical issues concerning the use of these diets. I have a copy of the program for the record.

The proceedings have been compiled in a book edited by Blackburn & Bray, which is expected to be off the press next month. We will be pleased to provide a copy of that.

Finally, Dr. Miller suggested the need for U.S. research into the safety and efficacy of the Cambridge Diet. He indicated that FDA's views on the experimental nature of diets providing less than 800 calories per day were most unlikely to change until that was warranted by research performed in this country, subjected to peer review and published in reputable medical journals.

We have accordingly funded research projects at the University of California at San Diego, the Universities of Rochester, Virginia, and Colorado, and at Yale University. Some results of this research have been published, and others are in prepublication stages or nearing completion. From the reports we have seen to date, the efficacy of the diet is clearly evident. No safety concerns have been raised. A summary of these projects is provided for the record.

As we began to support this research and to address the scientific issues, it became evident that we needed greater in-house scientific capability. We had previously relied on outside consultants. We added Dr. William Helby, an M.D. director, formerly with NASA in the space medicine program, a registered nurse, and a nutritionist-dietician. We felt we needed greater scientific depth.

In 1983, we were fortunate to be able to employ Robert O. Nesheim as our vice president of science and technology. Dr. Nesheim has guided us in changing our programs in light of new research data and the medical and regulatory criticism.

To encourage greater physician involvement in our programs, our medical departments, in conjunction with Dr. Nesheim, has developed a brochure entitled, "Physician's Guidelines for the Use of Very Low Calorie Diets," which we distribute to physicians without cost. I submit a copy for the record.

In the past month, we have published a booklet entitled "Physician's Manual: Management of Obesity," a nonpromotional piece provided to physicians who request it. We think it is a unique professional publication which will be a valuable aid to physicians directing weight-management programs. As physicians' understanding of this complex problem increases, we hope that their understanding and acceptance of our Cambridge programs will also increase. I have a copy of the manual for the record.

I would like to outline for the committee our current plan that we offer the general public. The plan offered gives a choice of three basic systems, each of which involves the consumption of approximately 800 calories per day. We call the three programs the Cambridge Food for Life System. The original 330 calorie diet product is part of one of the plans, under which it is to be used with a small daily meal of 400 to 500 calories.

A second plan is based on a new product, the Cambridge 420 Diet, which provides 100 percent of the U.S. RDA for protein and 420 calories per day. This is also to be used with a small 400 to 500 calorie meal except when a physician advises that the dieter consume only the 420 product.

Our third plan involves another new product called the Cambridge 800 Diet. It is a self-contained formula providing 800 calories per day. It provides an exclusive source of nutrition for those dieters who cannot stay on a controlled caloric program of conventional foods. The overall system is described in our program book which I submit for the record.

We believe that these actions reflect a responsible and consistent effort to meet the criticism leveled at our original program.

As my last point, I would like to describe the changes in our marketing program. At the heart of our original program was the belief that effective weight loss requires not only a product, but also psychological support to go along with it. That is why we adopted a direct sales system in the first place, and why we have been unwilling to abandon it.

We believe that successful weight loss requires a well-designed program with these elements:

One, physician overview to minimize health concerns;

Two, a commitment by the person wishing to lose weight to agreed weight-loss goals;

Three, a nutritionally sound product used in a disciplined program; and

Four, support to keep the dieter on track and guided toward new eating habits.

We also believe that a rapid initial weight loss is important because it encourages and motivates the dieter. We view that as a key feature of a very low calorie diet.

To meet these needs, we have made major changes in our marketing system since 1983. When we installed our direct sales system in 1981, we wanted a program under which our distributors would provide support and meet the psychological needs of dieters, not as professionals but as peers—that is, persons who had successfully used the Cambridge diet. However, we were new to direct marketing. Coupled with a popular new diet, the system of multitiered financial incentives which we devised triggered an unmanageable growth and a distributor network that was quickly out of our control.

We had envisioned sales groups that would be trained and managed by responsible leaders. In fact, they were scattered across the country in a random, willy-nilly way that made training and control impossible. Our multitiered structure of bonuses, coupled with the great demand for our product, attracted sales people looking for quick riches but with little interest in supporting dieters.

Our sales climbed steeply during early 1982 and then fell just as steeply in late 1982 and early 1983. In September 1983, we filed a chapter 11 proceeding.

Today, we have in place a sales program in which the incentives and controls are consistent with our goals of service and support. Rather than sell our product off the shelf in retail stores, we have preserved the counselor system of direct sales because we believe that system can provide the support necessary to enduring weight loss.

However, we have brought that system under better control by employing regional directors to conduct regional training, and by eliminating the unrestricted geographic dispersion of sales units. We have abandoned multitiered bonuses in favor of a compensation structure which rewards effort and provides lower but more stable financial incentives to persons who will provide the support and encouragement which is the cornerstone of our program.

In conclusion, while we see a number of bright signs, I do not know if the Cambridge Diet products and programs will find a permanent niche in weight reduction in this country, but if we read the evidence correctly—if very low calorie diets in properly designed programs do offer promise in this frustrating area—then it would be a serious loss if that effective tool disappears.

We believe the Food-for-Life system that we offer today is scientifically sound and is both safe and effective.

We thank you, Mr Chairman and members of the subcommittee, for this opportunity to tell you and others what we are doing. Dr. Nesheim and I will be more than happy to respond to questions the committee has.

Chairman ROTH. Mr. Feather, one of the principal points you make in your well-designed program is, one, physician overview to minimize health concerns. Is it your viewpoint to undergo this kind of a weight-loss program that it is important for reasons of safety that the taker of these so-called Food-for-Life systems should be under the direction of a doctor?

Mr. FEATHER. It depends on the individual dieter. I would say, yes, if those people have any medical condition. If they do not, then what is important is the people go through a self-selection. What we make sure is that whether the Cambridge counselor does his job or not—in other words, give the people proper instruction for use of the product makes them aware of the medical notice, that those people are made aware that the company says if they should go on this program, like any new diet, like any exercise regimen after seeing their own doctor and those people will make their own decisions as to whether they see their doctor or not.

Chairman ROTH. On your label, do you have some kind of warning with respect to medical overview?

Mr. FEATHER. Yes.

Chairman ROTH. What does it say?

Mr. FEATHER. This is a medical notice that was arrived at out of an initial regulatory act that the FDA and the Post Office mandated as part of an action that they took 2 months after the program was introduced. As part of that action that they brought, we agreed to take the information as to who should properly use the product and put it into a mandated statement which is to be part of every promotion we have of the Cambridge product.

Voluntarily we have decided to put that on our label as well as on all our literature.

Chairman ROTH. If I understand your testimony, you say that an individual should seek the advice of a physician if he has any health concerns; is that correct?

Mr. FEATHER. If he has any medical symptoms.

Chairman ROTH. What do you mean by "medical symptoms?"

Mr. FEATHER. That is what the medical notice is to do, to provide language which specifies those types of conditions under which people should not be dieting and those types of conditions——

Chairman ROTH [interposing]. Would you read what the label says?

Mr. FEATHER. Yes. "Important notice. Please read." In bold.

> Consult your doctor before starting this diet. In particular, individuals who have heart and cardiovascular conditions, stroke, kidney disease, diabetes, gout, hypoglycemia, chronic infections, the very elderly, growing children, adolescents or anyone under medical care for any other condition should diet only under direct medical supervision. Your doctor can advise you whether you have any of the above conditions or for any reason should not be on this or any other diet. We will be happy to work along with you and your doctor to see that you achieve the exact results de-

sired. Pregnant women and nursing mothers should not be on any weight-loss program.

Chairman ROTH. You say you have brought your salesmen under the control of regional directors, and that you have better control because of this training. What does this training include in the area of medical advice?

Mr. FEATHER. It does not attempt to make our Cambridge counselors act as doctors. As a matter of fact, it is the exact opposite. The area regarding the role of the physician is to make sure there are regional directors trained. Their obligation before starting anyone on the product is to make them aware what the products are, their proper use, the medical notice and the advice they see their doctor before starting this program.

Also, to solicit if those people have any medical conditions. If they do, it is to ensure the products are not sold until the people have actually gone to see their doctors.

Chairman ROTH. Are these instructions in writing?

Mr. FEATHER. Yes, they are.

Chairman ROTH. Would you submit a copy of them for purposes of the record?

Mr. FEATHER. Yes.

Chairman ROTH. We will accept these as exhibit No. 15.

[The cover letter for exhibit No. 15 may be found on p. 375 and the balance of the submission may be found in the files of the subcommittee.]

Chairman ROTH. Would you please give the subcommittee some idea of the size of your company, your sales volume right now and its size prior to the chapter 11 filing?

Mr. FEATHER. Yes. Right now, we are about a $15 million a year business.

Chairman ROTH. What were you at the peak before the bankruptcy?

Mr. FEATHER. Our peak was 1982 in which our sales were a little over $380 million.

Chairman ROTH. Can you tell us briefly why Cambridge filed under chapter 11?

Mr. FEATHER. We ran out of money. [Laughter.]

Chairman ROTH. Is it accurate to say the Cambridge marketing plan had gotten out of control?

Mr. FEATHER. That is very accurate, Senator.

Chairman ROTH. If so, would you explain why this occurred?

Mr. FEATHER. Yes, I will try to. It is a complex issue that we spent 2 or 3 hours with Mr. Rinzel trying to elaborate.

Chairman ROTH. Try to be brief. [Laughter.]

Mr. FEATHER. Yes, I will do that. When we started the program, we had the extent of matching up a very good nutritional tool that we felt would be a fundamental part of a successful weight reduction program. We felt the way to do that would be to find successful users and then give them opportunity to build up sales organizations of other successful users. We had no experience in direct marketing programs, so we searched around for a program we thought would be applicable to the Cambridge Diet and we copied our program roughly after Mary Kay, after Mary Kay's program.

The problem was that in our program, we had no limit on how and where people could recruit part of the sales force and what we got was sort of a land rush. The enthusiasm, excitment of our initial Cambridge counselors and their own personal experience made it very easy for them to recruit people to go on the program and, subsequently, be sales people.

Because people got commissions on layers of sales people that were recruited by the people that they brought in, so on, so forth, there was an incentive to go do as much recruiting as you possibly could. We had instances of people just circling the United States trying to sign up as many Cambridge counselors as they possibly could, which made obvious control, training, continuity, stability—made it impossible.

The marketing plan was running the company more so than the management of Cambridge Plan International. And we felt that not only was that not something we were controlling, but it was running contrary to our goal of making sure people really understood their role as a Cambridge counselor in providing the Cambridge dietary formula.

When the sales took and the additional people involved in Cambridge in building these organizations made lots of money, rather than selling the diet, what they were really doing was selling an opportunity and expectations and that attracted people who were not interested so much in the diet but an opportunity to make lots of money.

When the market changed, it became more difficult to get people on the diet and recruit people. There was disenchantment. The expectations created by the first people in making lots of money were not being realized and the drug sales business is a momentum business; it's an enthusiasm either going up or down. When disenchantment set in, sales dropped dramatically and our ability at one time to be able to stay up with growth was the thing that allowed us to keep the thing open. But as suddenly as we were trying to get all the computer equipment, buildings, personnel, to stay up with the growth, sales turned down; we had tremendous liquidity problems. Cash we had gotten in the early days went to try and fuel greater growth, and we eventually just ran out of cash and needed time to liquidate no longer hard assets to try and stay in business.

Chairman ROTH. In other words, if I understand what you are saying, the problem was the driving force behind the marketing was to make, shall we say, a fast buck rather than to market a nutritional diet program?

Mr. FEATHER. Yes, a lot. Not initially, but that's exactly what it came to be. People who had not made very much money were suddenly making huge amounts of money and recruiting was taking place not so much by featuring the diet as it was by featuring bonus checks.

Chairman ROTH. Why is there a need for a 330-calorie-per-day product when you now market a 420-calorie-per-day product and when, according to your statement, Cambridge recommends an 800-calorie-per-day plan?

Mr. FEATHER. The 800-calorie-per-day plan is something we found out through user experience provides satisfactory results. I do not believe that it provides the same results as a 330-calorie plan. Obviously, you lose weight faster on 330 calories than you do on 800 calories, and people are not as hungry on a 330-calorie formula regimen as they are on one in which they start taking conventional foods.

We found out that despite the fact we only had one product and one program when we started, 80 percent of our users were not following our plan. In fact, on their own were adding a meal and were doing it successfully. So we found out that human nature was such that in terms of complying to the program, the 800-calorie program was one that a majority of the people would comply with. We found out their results in losing weight were satisfactory and allowed us to fall much more into compliance with conventional wisdom on the part of the medical community and FDA.

I might offer, Senator, Dr. Nesheim on my left is the one who really helped us design our new Food-for-Life System. In terms of elaboration on the difference and the rationale for developing that, he might give helpful information to your committee.

Chairman ROTH. Let me proceed, if I may, for a moment with you. My time is almost up. Isn't the marketing of a 330-calorie product an indirect invitation to consumers to use it as a sole source of nutrition?

Mr. FEATHER. I think some may. We found out that when that was the only program we promoted, most of the people didn't do it. It would have to assume now we tell people not to do it, we will get even fewer people to do so. I think one of the important things is it is safe. The program of 330 calories a day sole source was one that was well researched before it was marketed, and we subsequently have done a great deal of American clinical studies that support the safety issue of 330 calories sole source.

Chairman ROTH. Let me ask you this. As I understand it, Cambridge now recommends an 800-calorie plan; is that correct?

Mr. FEATHER. That's right.

[At this point in the hearing, Senator Chiles reentered the hearing room.]

Chairman ROTH. How do you square that with what appears to be an endorsement of a 330-calorie diet?

Mr. FEATHER. We really don't endorse it, Senator. In all of our literature and training we do of our Cambridge counselors, we let them know the program we have is very important they outline exactly. There are three choices under 800 calories. I think the confusion is we have not had much luck in getting any credit to changes we have made, and all the current articles that have been published on the Cambridge Diet, very little recognition change was made in our program. There really was very little recognition by the FDA that there was change made in our program.

It is something we are fighting to do, the perception we have changed. The programs we have right now, they are effective, they are safe and they are now much closer to the conventional wisdom on what is an appropriate amount of calories for a reducing diet.

Chairman ROTH. My time is up. Senator Rudman.

Senator RUDMAN. Thank you, Mr. Chairman. I will be very brief. We do have a vote. At any time during the corporate history of your company, did your company in any of the literature that it prepared, either written or video material or otherwise, make any other stated claim for the product other than the fact if you took it, you lose weight?

Mr. **FEATHER**. No, not to my knowledge.

Senator **RUDMAN**. You would have that knowledge, wouldn't you?

Mr. **FEATHER**. I certainly should.

Senator **RUDMAN**. You have been chief executive officer of this company since its beginning?

Mr. **FEATHER**. I have.

Senator **RUDMAN**. So there was none and there is none?

Mr. **FEATHER**. That's correct.

Senator **RUDMAN**. You say the product will cause weight reduction; that is all you say?

Mr. **FEATHER**. That's right.

Senator **RUDMAN**. The basic issue about the product was whether or not that 330-calorie diet might have some adverse effects on the general public that might not have been foreseen by your research; is that correct?

Mr. **FEATHER**. That's roughly it. The criticism was really can you get along with eating as little food as 330 calories.

Senator **RUDMAN**. Now, you said you had done some research on this and your company before you introduced the plan?

Mr. **FEATHER**. No.

Senator **RUDMAN**. You did not say that?

Mr. **FEATHER**. We did not. We have been aware of the great body of research that had been conducted in the 1970's.

Senator **RUDMAN**. By others?

Mr. **FEATHER**. That's right.

Senator **RUDMAN**. Who had said that you could generally use 330 calories a day irrespective of your physical condition and that was all right?

Mr. **FEATHER**. If you had medical problems, you were excluded from that group, but if you were in general health and obese, that's correct.

Senator **RUDMAN**. How much money was spent on the formula that was patented and that you actually purchased? Do you know how much money was spent on research on that program?

Mr. **FEATHER**. No, I don't.

Senator **RUDMAN**. Did you know at the time?

Mr. **FEATHER**. No.

Senator **RUDMAN**. Do you think maybe in retrospect possibly before you make representations that you ought to at least check on the kind of research that was done?

Mr. **FEATHER**. We certainly have checked on the kind of research done. I don't know exactly how much the research cost. Research was done at reputable universities and was done based on design set up by large pharmaceutical companies to approximate the kind of studies you do for drugs, not foods. So it passed the safety test that would be designed for a new drug coming into the marketplace.

Senator **RUDMAN**. However, at this point for a variety of reasons you labeled these products; is that correct?

Mr. **FEATHER**. Yes.

Senator **RUDMAN**. What did the label say again, in terms of the warnings that might be on the labels?

Mr. **FEATHER**. Would you like me to read it again?

Senator **RUDMAN**. Unless it is too long.

Mr. **FEATHER**. "Important notice. Please read. Consult your doctor before starting this diet. In particular, individuals who have heart and cardiovascular conditions, stroke, kidney disease, diabetes, gout, hypoglycemia, chronic infections, the very elderly, growing children, adolescents or anyone under direct medical supervision. Your doctor can advise you whether you have any of the above conditions or for any reason should not be on this or any other diet. We will be happy to work along with you and your doctor to see that you achieve the exact results desired. Pregnant women and nursing mothers should not be on any weightloss program."

Senator **RUDMAN**. Did you put that on there because you had an honest concern of people improperly using your diet or because you were pressured into doing it? Which of the two?

Mr. **FEATHER**. We put it on there voluntarily, Senator, and we believe that it is good information. We believe it is an important part of the program and very helpful in people getting proper use of the diet.

Senator **RUDMAN**. That recommendation was made to you by the professional person you hired to come in and work with your company to make the product not only more marketable but also to meet whatever Federal standards might be applied to it?

Mr. **FEATHER**. Well, this exact language came out of our consent decree with the Food and Drug Administration and the U.S. Post Office. This exact language came out of that. Our decision to put it on our products was a voluntary one. The consent decree only specifies we put it as part of our promotions, yet you will find it throughout our literature almost to the point where you can't avoid it. It is there over and over again. It is there because we think it is a very important and responsible thing for us to be able to ensure; even if our counsellors do not do their job, side step the issue of making people aware of it, the consumers will be aware of the proper use of the medical notice.

Senator **RUDMAN**. How long have you been in this business, Mr. Feather?

Mr. **FEATHER**. Cambridge was started in 1980.

Senator **RUDMAN**. Before that, you were also in a similar business?

Mr. **FEATHER**. I have been in the health business since I was 20 years old.

Senator **RUDMAN**. Do you believe in your view—I guess you are expert as you can get in terms of being in this business—do you believe any product that is for weight reduction should be marketed without a warning to certain classes of people based on your own experience? Classes of people being those you read on your own label? I want your own view, not what somebody made you do—what you think.

Mr. **FEATHER**. Well, there are a wide variety of dietary products. I have been aware of some, have seen some over the last few days, and I would think it is very appropriate that something be done to protect the general public from fraudulent dietary products.

[At this point in the hearing, Senator Gore withdrew from the hearing room.]

Mr. **Feather**. I certainly think it would be appropriate as a citizen to ensure something like the liquid protein doesn't get put on the market without some sort of regulation that prevents it from coming on the market.

Senator **Rudman**. I assume you also think that people with heart disease, liver disease, and diabetes and other critical ills of that sort, with a product that is supposedly going to lose weight on low calories, there ought to be a warning that says you better check with your doctor before you take this product exclusively?

Mr. **Feather**. Yes; I think that is right.

Chairman **Roth**. The subcommittee will be in recess.

[Brief recess.]

[Senators present at the time of recess: Senators Roth, Rudman, and Chiles. Senators present at the time of reconvening the hearing: Senators Roth and Rudman.]

Chairman **Roth**. The subcommitttee will please be in order. Senator Rudman, do you have any further questions?

Senator **Rudman**. I believe I am through, Mr. Chairman. I think we covered the ground I wanted to cover with these witnesses. There, obviously, is a dispute, a different nature of dispute than some of the others we have heard. I compliment the chairman on the weight reduction program of this subcommittee. He usually doesn't have lunch. [Laughter.]

Chairman **Roth**. Thank you, Senator Rudman. Mr. Rinzel.

Mr. **Rinzel**. Dr. Nesheim, could you give us a little bit about what your credentials are, background? I know you have a Ph.D. in nutrition.

Dr. **Nesheim**. Ph.D. in nutrition, University of Illinois. I was employed by Quaker Oats Co. 28 years before I retired and went to work for Cambridge Plan International 2 years ago. I have been on the Food and Nutrition Board of the National Academy of Science for 6 years. I have been on several of their committees and chaired many of them. I have been chairman of the industry liaison panel, American Medical Association. I was on the Food Advisory Committee of the Office of Technology Assessment for U.S. Congress. I am a member of the American Institute of Nutrition, the American Public Health Institute.

[At this point in the hearing, Senator Cohen reentered the hearing room.]

Mr. **Rinzel**. You have had a chance, of course, to review the warnings on the Cambridge label?

Dr. **Nesheim**. Yes.

Mr. **Rinzel**. In your professional opinion, are those warnings appropriate for use of these products?

Dr. **Nesheim**. Yes, they are. I would certainly believe that warnings of that kind ought to be on products of this kind.

Mr. **Rinzel**. I have no further questions.

Chairman **Roth**. Thank you, Gentlemen. That concludes the questions for you.

[The joint prepared statement of Messrs. Feather and Nesheim follows:]

STATEMENT OF
VAUGHN FEATHER
PRESIDENT,
CAMBRIDGE PLAN INTERNATIONAL
and
ROBERT O. NESHEIM, PH.D.
SENIOR VICE PRESIDENT
SCIENCE AND TECHNOLOGY,
CAMBRIDGE PLAN INTERNATIONAL
BEFORE THF
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
COMMITTEE ON GOVERNMENT AFFAIRS
UNITED STATES SENATE
on
INVESTIGATION OF
WEIGHT CONTROL PRODUCTS
May 15, 1985
Washington, D.C.

STATEMENT OF
CAMBRIDGE PLAN INTERNATIONAL

My name is Vaughn Feather, and I am the President of Cambridge Plan International. Since 1980, Cambridge Plan International has distributed in this country a very-low-calorie dietary formulation known as the Cambridge Diet, as part of a program for persons seeking seriously to lose weight. With me today is Dr. Robert O. Nesheim, Ph.D., our company's Senior Vice President for Science and Technology.

From our standpoint, this investigation is a welcome one. We believe that a balanced and nutritionally fortified very-low-calorie diet such as ours, when offered as part of a well-considered support system, offers genuine promise in the area of weight reduction. Since 1982, when publicity concerning the Cambridge Diet was at its peak, our products and programs have undergone major changes. We welcome the investigation for the opportunity it gives us to explain those changes.

I. THE PROBLEM OF OBESITY

First, I would like to comment on the long-recognized health implications of overweight and obesity. The severity of this problem was recently emphasized in the report of the Consensus Conference on The Health Implications of Obesity sponsored by the National Institute of Health, of which I am sure you are aware. Public announcements following the conference characterized obesity as a killer disease comparable to cigarette smoking.

That obesity remains unchecked despite being identified as a major health concern suggests that the conventional prescription for it -- the advice to exercise more and eat less conventional foods -- has not been successful. If that worked, obesity would not be the problem that it is today.

We believe there is a need and a place for responsible commercial weight reduction programs and products which are administered with the cooperation and assistance of physicians, but which do not make unacceptable or unrealistic demands on the available time and resources of the medical community. In the Cambridge Plan as it presently exists -- after five years of experience and with important changes from its early days -- we think we may have such a program.

II. THE ORIGINAL CAMBRIDGE DIET

Our company started in 1980 with a single product, the Cambridge Diet. Although its safety and efficacy was supported by research at leading European institutions, the Diet ran against the conventional wisdom, and we found ourselves in an unexpected storm of controversy. We have been working ever since to gain broad medical acceptance of our products and programs.

The Original Cambridge 330 Calorie Diet. The Cambridge Diet with which we started was a very-low-calorie formulation conceived in the early 1970's by Alan N. Howard, Ph.D., of Cambridge University. During the 1970's it was tested at various European research centers, in addition to Cambridge. I have for the record a list of published research on this and other very-low-calorie diets.

The original Cambridge Diet was comprised of a natural food base -- nonfat dry milk and soy flour -- enriched with 100% of the U.S. RDA of vitamins and minerals, with trace elements and electrolytes, to create a nutritionally dense formulation providing 330 calories per day. It was originally marketed by Cambridge Plan to be used as an exclusive source of nutrition for periods of up to four weeks, to be followed in turn by a week of recommended low calorie meals, followed if necessary by further use of the Diet as a sole source of nutrition. The four-week period was based on the views of the European researchers concerning unsupervised use of the Diet.

III. EFFECTIVENESS OF THE CAMBRIDGE DIET

One of the two key questions to be asked of any diet or weight-loss program is whether it is effective. That does not mean whether it produces quick or immediate weight loss -- most diets, good and bad, do that -- the test is whether the weight-loss is enduring. Very few diet programs pass the test.

Two-year Follow-up. There is evidence that the Cambridge Diet program can provide enduring weight loss. In 1982, we identified over 800 persons who had lost 50 pounds or more on the Cambridge Diet. For the next two years, the Opinion Research Corporation of Princeton, New Jersey, conducted annual telephone surveys of those persons. To persons familiar with diet failure rates, the results of their survey have been quite surprising.

Two-year data are available on 354 of these persons. This group originally weighed an average of 250 pounds. Their original mean weight loss was 60.8 pounds. After one year they had maintained on the average all of that weight loss. After two years, 42 percent had maintained their entire original weight loss, or had lost more weight. As a whole, the group had maintained on the average over 48 of the original 60 pounds of weight loss.

Although they do not represent a random sample of a normal population, we believe the enduring weight loss realized by these quite obese individuals is quite significant. The continued use of the Cambridge Diet in a maintenance program in the year following their initial weight loss appears to have contributed significantly to their success.

IV. SAFETY OF THE CAMBRIDGE DIET

The other key question is of course safety. When we introduced the Cambridge Diet in this country, we relied upon the results of the European clinical tests, which supported its safety, and on the fact that the European physicians and scientists who conducted those tests had concluded that the Diet was safe for unsupervised use for periods of six weeks or more.

Usage of the Cambridge Diet: 1981-82. We have also tried to evaluate the experience of consumers of the Cambridge Diet. To secure reliable evidence of usage, we commissioned Professor James Carman of the Graduate School of Business of the University of California to conduct a projectible survey to determine how many persons had used the Diet in this country during 1981-82.

Professor Carman's survey, which was concluded in November, 1982, determined that during a 21-month period of 1981-82 five million Americans used the Diet. Of these, about 850,000 apparently used it as a sole source of nutrition for four weeks or longer. The rest, over four million, used the diet differently, most commonly with a small daily meal. Professor Carman's survey is to be published next month as part of a book. I have for the record a copy of his report.

Complaints. In contrast to the five million users of the Cambridge Diet during this 21-month period, our company has received -- over the entire five years we have been in business -- about two hundred complaints of consumer injury. One hundred and sixty of these -- or about 80 percent -- relate to salmonella found in an ingredient sold to us by a supplier in mid-1982. This resulted in a voluntary product recall. The rest of the complaints over this five-year period -- forty in all -- relate predominantly to problems of a transient nature attributed by consumers, rightly or wrongly, to use of the Diet. For the past two years we have received no complaints at all.

As we have informed the Subcommittee's counsel, we have received five serious complaints asserting that the Diet caused deaths. Three of these resulted in lawsuits, and two have not been pursued. Of the three, one was not on our weight-loss program, and the other two shared no common pattern. In the one case where complete medical records exist, the records have been reviewed by four independent medical experts, including some of the leading U.S. authorities on very-low-calorie diets, and each of them concluded that the death was not caused by dieting.

I believe FDA has investigated these and similar reports. As I understand it, FDA does not contend that the evidence shows that the Cambridge Diet was a cause of any of the incidents it has investigated, although it has also been unwilling to exonerate the Diet.

It is appropriate to ask why the Diet has been linked to these incidents. I think the answer lies in a combination of factors. First, the Cambridge Diet was introduced in this country shortly after the 1978 experience with liquid protein, which was a very different, and dangerous, diet. Liquid protein and the havoc that it caused left an understandable aftermath of concern and uncertainty. Indeed, during our early years it was not uncommon for the media and some medical authorities to refer to the Cambridge Diet as a "liquid protein" diet, and to be unwilling or unable to distinguish these two very different diets.

Second, the safety of the Cambride Diet received a great deal of highly publicised criticism in the press and on television based on the conventional view that there is something risky about any diet of less than 800 calories per day. In the midst of all this, the Cambridge Diet was being used in this country on a scale which was probably unprecedented.

I believe that these matters frightened users of the Diet; I think they created a climate of alarm in which consumers were influenced to link to their use of the Diet ailments and medical problems which would have occurred even if they had not been dieting.

Again, over a five-year period and out of more than five million users, we have received only forty complaints.

IV. RESPONSE TO CRITICISM OF THE CAMBRIDGE DIET

While we have not agreed with it, we have tried to adapt to the medical criticism of the Cambridge Diet. For the most part the criticism of our 330 calorie regime was academic or theoretical in nature -- that is, it was based on the widely-held view that a diet of less than 800 calories is unsafe, rather than on evidence of actual injuries. This nevertheless made it increasingly difficult to market our program, and it caused us to re-evaluate that program. It is important to understand that many of the steps I am about to describe occurred at a time when we were operating under severe financial constraints, and after our company had filed a proceeding under Chapter 11 of the Bankruptcy Code.

The basic criticism leveled at the Cambridge Diet was that the Diet was so low in calories as to be unsafe unless taken under medical supervision. Professor Carman's survey had disclosed, however, that over 80 percent of our customers were not adhering to the criticised 330 calorie per day program, but were nevertheless achieving acceptable weight loss. Despite our belief in the Diet's safety, we eventually concluded that we could modify our 330 calorie program to avoid the criticism without significantly lessening its effectiveness. We thereore changed our programs in ways that I will describe later.

During this same period, we sought to establish a better relationship with the Food & Drug Administration. While we did not agree with FDA's public position on the Cambridge Diet, we recognized its duty to take a conservative position regarding our product, and we felt that it acted in a responsible and appropriate manner toward our company.

In late 1982, I requested a meeting with Dr. Sanford Miller, Director of the then Bureau of Foods, to discuss our operations and products. At that meeting, Dr. Miller made three basic suggestions, which we tried to follow.

Baby Food Quality Assurance Standards. First, Dr. Miller suggested that because the Cambridge Diet was sold for use as an exclusive source of nutrition, we adopt the quality assurance standards then proposed for the manufacture of baby foods, despite the fact that the baby food regulations did not apply to our products. We followed that suggestion. Since early 1983, the quality assurance procedures used in the manufacture of our Cambridge Diet products have been based on those guidelines.

Medical Critics: Cape Cod Symposium. Second, Dr. Miller suggested that we establish a dialogue with our critics -- solicit their views, explain our position, present our evidence, and so forth. To this end, Cambridge Plan funded in June, 1983 a symposium on very-low-calorie diets. It was organized by Drs. George Blackburn and Fred Stare of Harvard University and Dr. George Bray of the University of Southern California. Thirty participants from five countries attended, and addressed scientific and clinical issues concerning the use of these diets. I have a copy of the program for the record.

We have underwritten the publication of the proceedings of the Symposium. They have been compiled in a book edited by Drs. Blackburn and Bray which is expected to be off the press next month. We will be pleased to provide a copy then. While the scientific discussions presented in the book were wide-ranging, a key focus was the extent of medical supervision required for persons using a very-low-calorie diet program.

United States Research. Finally, Dr. Miller suggested the need for U.S. research into the safety and efficacy of the Cambridge Diet. He indicated that FDA's views on the experimental nature of diets providing less than 800 calories per day were most unlikely to change until that was warranted by research performed in this country, subjected to peer review and published in reputable medical journals.

We have accordingly funded research projects at the University of California at San Diego, the Universities of Rochester, Virginia and Colorado, and at Yale University. Some results of this research have been published, and others are in pre-publication stages or nearing completion. From the reports we have seen to date, the efficacy of the Diet is clearly evident, and no safety concerns have been raised. A summary of these projects is provided for the record.

We think the publication of this research will add importantly to the knowledge of the use of very-low-calorie diets in the treatment of obesity-related metabolic disorders, and to an understanding of their safety.

In-house Scientific Guidance. As we began to support this research and to address the scientific issues, it became evident that we needed greater in-house scientific capability. We had previously relied on outside consultants. We added an M.D. Medical Director, a registered nurse and a nutritionist-dietitian, but we felt we needed greater scientific depth.

In 1983, we were fortunate to be able to employ Robert O. Nesheim as our Vice President of Science and Technology. Dr. Nesheim has guided us in changing our programs in light of new research data and the medical and regulatory criticism.

Physician Participation. As they sought greater physician involvement in our programs, Dr. Nesheim and our medical advisors found that physicians in general were not very knowledgeable about what to look for when monitoring patients on very-low-calorie weight-loss programs. Based on our own experience and in consultation with clinical investigators, our medical department developed a brochure entitled "Physician's Guidelines for the Use of Very-Low-Calorie Diets," which we distribute to physicians without cost. I submit a copy for the record.

In the past month, we have published a booklet entitled "Physician's Manual: Management of Obesity," a non-promotional piece provided to physicians who request it. We think it is a unique professional publication which will be a valuable aid to physicians directing weight-management programs. As physicians' understanding of this complex problem increases, we hope that their understanding and acceptance of our Cambridge Programs will also increase. I have a copy of the Manual for the record.

Current Cambridge Programs. Unlike our original program, which was based on a single product providing 330 calories per day, our current plan offers a choice of three basic systems, each of which involves the consumption of approximately 800 calories per day. We call the three programs the Cambridge Food For Life System. The original 330-calorie diet product is part of one of the plans, under which it is to be used with a small daily meal of 400-500 calories.

A second plan is based on a new product, the Cambridge 420 Diet, which provides 100% of the U.S. RDA for protein and 420 calories per day. This is also to be used with a small 400-500 calorie meal except when a physician advises that the dieter consume only the 420 product.

Our third plan involves another new product called the Cambridge 800 Diet. It is a self-contained formula providing 800-calories per day; it provides an exclusive source of nutrition for those dieters who cannot stay on a controlled caloric program of conventional foods. The overall system is described in our program book which I submit for the record,

Under all of our plans, consumers are told to consult their physician before starting a diet. This is repeated throughout our product literature and appears on the labels of our products. I have three product labels for the record.

The Food for Life System was introduced in early 1984. Our ability to provide it with visibility to consumers and to medical and nutritional professionals has been seriously handicapped by the severe financial constraints under which we have operated since the Chapter 11 proceeding was filed in 1983.

We have kept the FDA informed of these changes and of our expanded effort to communicate them to the medical community.

We believe that these actions reflect a responsible and consistent effort to meet the criticism leveled at our original program. They show our company's good faith and its commitment to the development and marketing of safe and effective weight-management programs.

V. NEW MARKETING SYSTEM

As my last point, I would like to describe the changes in our marketing program. At the heart of our original program was the belief that effective weight loss requires not only a product, but also psychological support to go with that product. That is why we adopted a direct sales system in the first place, and why we have been unwilling to abandon it.

We believe that successful weight loss requires a well-designed program with these elements:

1. Physician overview to minimize health concerns;
2. A commitment by the person wishing to lose weight to agreed weight-loss goals;
3. A nutritionally sound product used in a disciplined program; and
4. Support to keep the dieter on track and guided toward new eating habits.

We also believe that a rapid initial weight loss is important because it encourages and motivates the dieter. We view that as a key feature of a very-low-calorie diet.

To meet these needs, we have made major changes in our marketing system since 1983. When we installed our direct sales system in 1981, we wanted a program under which our distributors would provide support and meet the psychological needs of dieters, not as professionals but as peers -- that is, persons who had successfully used the Cambridge Diet. However, we were new to direct marketing. Coupled with a popular new diet, the system of multi-tiered financial incentives which we devised triggered an unmanageable growth and a distributor network that was quickly out of our control.

We had envisioned sales groups that would be trained and managed by responsible leaders. In fact, they were scattered across the country in a random, willy-nilly way that made training and control impossible. Our multi-tiered structure of bonuses, coupled with the great demand for our product, attracted sales people looking for quick riches but with little interest in supporting dieters.

Our sales climbed steeply during early 1982 and then fell just as steeply in late 1982 and early 1983. As I said, in September 1983 we filed a Chapter 11 proceeding.

Today, we have in place a sales program in which the incentives and controls are consistent with our goals of service and support. Rather than sell our product off the shelf in retail stores, we have preserved the Counselor system of direct sales because we believe that system can provide the support necessary to enduring weight reduction. However, we have brought that system under better control by employing regional directors to conduct regional training, and by eliminating the unrestricted geographic dispersion of sales units. We have abandoned multi-tiered bonuses in favor of a compensation structure which rewards effort and provides lower but more stable financial incentives to persons who will provide the support and encouragement which is the cornerstone of our program.

VI. CONCLUSION

While we see a number of bright signs, I do not know if the Cambridge Diet products and programs will find a permanent niche in weight reduction in this country. If we read the evidence correctly -- if very-low-calorie diets in properly designed programs do offer promise in this frustrating area -- then it would be a serious loss if that effective tool disappears.

We think it would be a shame if that happened.

We believe the Food For Life System that we offer today is scientifically sound and is both safe and effective.

SUMMARY

To summarize, I would like to leave these points with the Subcommittee:

* Our company began with a novel 330 calorie diet product backed by research at European hospitals and universities.

* That product encountered widespread criticism from the medical community in this country.

* Despite our belief in the safety of the original Cambridge Diet, we have, under the guidance of Dr. Nesheim and others, modified our weight reduction programs to meet this criticism while preserving the key elements an effective weight management program.

* Today, we offer a new Food for Life System which we believe provides a comprehensive package of uncontroversial nutritional tools for effective, lasting weight reduction.

We thank you, Mr. Chairman and members of the Subcommittee, for this opportunity to tell you and others what we are doing.

CAMBRIDGE PLAN INTERNATIONAL

STATEMENT

LIST OF ATTACHMENTS

1. Physician Mailer: Products and Programs
2. Physician Guidelines: Use of Very-Low-Calorie Diets
3. Physician Manual: Use of Very-Low-Calorie Diets
4. Physician Information Packet
5. Bibliography: Published Research on Very-Low-Calorie Diets
6. Labels: Cambridge 330, 420 and 800 Calorie Diets
7. Program Book: Cambridge 330, 420 and 800 Calorie Diet Programs
8. List of U.S. Research Projects on Very-Low-Calorie Diets Financed by Cambridge Plan International
9. Program: Cape Cod Symposium on Very-Low-Calorie Diets
10. 1982 Survey on Use of Cambridge Diet in America (in Gallery Proof)
11. Curriculum Vitae, Robert O. Nesheim, Ph.D., Senior Vice President, Science and Technology, Cambridge Plan Interantional

Chairman ROTH. We will next call Mr. Mark Hughes and Dr. David Katzin. Gentlemen, if you will continue standing—Congressman Dannemeyer, you don't have to. Dr. Katzin and Mr. Hughes, I would ask you to raise your right hand.

Do you swear the testimony you will give before the subcommittee will be the truth, the whole truth and nothing but the truth, so help you God?

Mr. HUGHES. I do.

Dr. KATZIN. I do.

Chairman ROTH. Please be seated. It is my great pleasure at this time to welcome Bill Dannemeyer who is a Member of Congress from the 39th District of California. He would like to introduce our next witness.

TESTIMONY OF HON. WILLIAM E. DANNEMEYER, U.S. CONGRESSMAN FROM THE STATE OF CALIFORNIA

Representative DANNEMEYER. Thank you, Mr. Chairman, and members of the subcommittee. The congressional district in California that I am privileged to represent, the 39th, includes the city of Orange. It is the location of the plant that produces the products that are sold and marketed under the name Herbalife. It employs about 200 people and so I have a casual interest in the matter that is now pending before your subcommittee.

Before coming to Congress, I have been involved in controversies of this nature involving food products, their sale and consumption. For over 20 years, I was general counsel for a producer of raw milk in California, and that producer is still having problems with the State of California in being able to market that product for consumers in our State. It was and is a continuing battle between the officials of the public health office in California and the producer of that product and the consumers who want to consume it involving largely the argument over nutrition.

That is why I have a little bit of empathy of this problem today. I am reminded of the words of the German philosopher Schopenhauer, who said truth passes through three stages. First it is ridiculed; second it is violently opposed; and third is it is accepted as being self-evident.

It is in this context I have the privilege of, I think, introducing Mr. Mark Hughes who is from California who was the moving spirit behind Herbalife. I respect the function of this subcommittee in holding these hearings. I think they are appropriate to be held at times when public interest is involved, and this subcommittee is certainly within its right to determine what the public interests should be on this issue.

I have long concluded from my study of nutrition in the case I have represented in California that what we Americans are going through is the fact that the food that we eat is the product of land that is being depleted in terms of nutrients. We are not putting enough back into the soil. As a result, American citizens understand there is something nutritionally lacking. Herbalife has developed a product, I think, that speaks to that, and it is in that sense that I commend it to your consideration.

[Congressman Dannemeyer's prepared statement follows:]

PREPARED STATEMENT OF CONGRESSMAN WILLIAM E. DANNEMEYER

Mr. Chairman, I want to take this opportunity to share some thoughts with the subcommittee on the subject of these hearings: weight-loss and weight-control programs. I do so as a member of Congress from California, where there is particular interest in this subject, and as a member of the House Energy and Commerce Subcommittee on Health and the Environment, which has jurisdiction over the Food and Drug Administration, among other agencies.

The citizens of my State and district are very health conscious, as are a growing number of Americans. Each individual pursues this interest in their own way with many looking to food products and dietary supplements as part of their regimen. I understand that the subcommittee is looking into a number of companies involved in this business, including Herbalife, whose products are manufactured by a company located in my district employing 200 people.

I certainly do not dispute the responsibility of State and Federal authorities, including this subcommittee, to look out for the public interest as each authority sees fit. Hearings are an essential part of Congressional oversight and the investigation of this subcommittee will add to the public discourse on the subject. As always, however, it is important to approach it with the appreciation that consumers should be allowed a maximum of freedom of choice to make decisions for themselves.

Those that make false claims or otherwise violate the law must answer at the bar of justice. We must not, however, indict a health program generally, or particular weight control products, merely because they are "unconventional" or "nontraditional" by the standards of the established medical profession.

I would leave the committee with the words of the German philosopher Schopenhauer: "All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident."

Representative DANNEMEYER. I would like at this time to present to the members of this subcommittee Mark Hughes, who is the moving spirit behind Herbalife. I thank you very much for your time.

[At this point in the hearing, Senator Cohen withdrew from the hearing room.]

Chairman ROTH. Thank you, Mr. Dannemeyer.

Mr. Hughes, would you proceed with your statement?

TESTIMONY OF MARK HUGHES, PRESIDENT AND FOUNDER, HERBALIFE INTERNATIONAL, ACCOMPANIED BY DAVID B. KATZIN, M.D., HERBALIFE MEDICAL/SCIENTIFIC ADVISORY BOARD, BARRY LEVINE, ESQ., AND DAVID R. ADDIS, ESQ.

Mr. HUGHES. Thank you, Mr. Roth. I believe you have my opening statement and have it entered into the record.

I appreciate the opportunity to be heard. I have been talked about over the last few days. I would like to begin by saying a little bit about how I developed the Herbalife Co. and how it got started.

For me, certainly the nutritional business is much more than a profit and moneymaking game. Diet and weight loss is something that has been part of my family for many, many years. I am appalled to see a lot of different weight products on the market. Just about everybody in my family had weight control problems, especially my mom. She went to doctors to get help and she was prescribed prescription drugs—Dexemil. She ended up getting hooked on it. This is a drug that makes you not be able to eat. It makes you not be able to sleep. From several years of using it, she ended up getting sleeping pills prescribed to her to go to sleep at night. Several years of using that, she ended up behind doctors' back seeing five and six to keep her habit up. She eventually died from an overdose.

To me, nutrition and helping people lose weight in the right manner is something important to me. I have sat here over the last couple of days and heard of a number of products about which very little attention has been paid and there have also been some very serious allegations, as far as I am concerned, about our products.

I have heard about these glasses that you wear; some kind of stupid rings you put in your ear, all the way to the more serious things that we have in our industry, like intestinal bypass operations; people getting mouths wired shut, and will do just about anything to try to lose weight.

In my opinion, and I don't think I am alone in this because right now there has been literally almost 10 billion portions of our product consumed at this particular time, I am not alone in saying I think our product is very safe, it is very sensible and it works.

It is primarily made up of protein, carbohydrates, fats, vitamins, and minerals. We have Dr. David Katzin here today who is prepared to show you a number of different studies that have been done on the products and efficacy of those products.

[At this point in the hearing, Senator Cohen reentered the hearing room.]

Mr. HUGHES. We heard just a few minutes ago about the Cambridge International Plan. There was some concern about whether those products should be used only under doctors' care and all this sort of thing. I don't know what they have at this particular point. I do know what they had in the beginning, which was a very dangerous product, as far as I am concerned, similar to the liquid protein diet where the body is only getting protein and not the proper amount of carbohydrates and vitamins and minerals.

As a result of not getting it from outside food intake, the body cannibalizes itself to get the nutrients. I think it is very hazardous, and I think the warning should be on the label.

I very much detest the fact that the subcommittee of this organization, especially Mr. Shapiro, testified in the beginning that there have been some allegations regarding to the deaths of people who have consumed Herbalife products. I want to make it perfectly clear, there have been no deaths as the result of anybody using Herbalife products. There has not been one lawsuit from this company of anybody dying from using these products. As a matter of fact, I saw a piece of paper floating around the room here yesterday about a Mr. Lee whose wife evidently accused Herbalife of causing her husband's death 6 months ago. It seems rather odd to me she wouldn't have sued this company 6 months ago as a result of her husband's death. I find it very odd that this subcommittee did not take the courtesy to at least pull up the autopsy report of the death.

We did it yesterday in approximately 10 minutes, and it showed that he died from natural causes and of heart failure. In fact, there are several people in the room who are football players who happen to have known Mr. Lee.

I take explicit offense since it has been quoted in several newspapers that there have been alleged deaths from the staff of this committee, that there have been several people who died. A name comes to mind, Miss Tyson. I don't understand why it was not brought forth yesterday to the news and to everybody else in this committee that Miss Tyson before she went on the products experienced four strokes before going on the products. She was paralyzed on her left side. She stopped using all her medication. She misused our products and went only on the Formula 1. She drank massive amounts of coffee, smoked cigarettes, attempted to lose 50 pounds in 5 days, stopped eating completely and died as a result of a heart attack.

I don't understand why this subcommittee has not brought forth some of this information. I hold a tremendous—I don't know what else to say.

I would like to say this. It seems if those people were going to make those kind of allegations against this company, the doctors who performed those autopsies should have been brought to this hearing instead of the so-called expert weight-loss people that were here yesterday. I think if they are so expert in weight loss, why were they so fat yesterday? [Laughter.]

I am not trying to make any jokes. I do think they ought to use our product. I don't understand it. I have lost 16 pounds on this product, and I have been in this business now for 10 years. As far as I am concerned, I am an authority in this particular industry.

There has been at this particular point 9,600,000,000 portions of this product consumed, and to this date, there have been 30 written complaints that the company has received. One of which is from a Mr. Little. He claims he went on the product, he withdrew suddenly from all social activities and friends. He broke up with his fiance and put an ad in the newspaper to meet women. He went on a wild shopping spree, experienced extreme shock and terror of depersonalization and damaged his car. I don't know exactly what you do about that, but I am very sorry he had those experiences.

I want it to be clear in this room here and on the record as I made it to Mr. Rinzel and Mr. Shapiro in a very nice manner and on a voluntary basis in a meeting in which I sat with the gentlemen and told them this:

Herbalife is here to be in business forever, and it is here to cooperate. It has cooperated with the FDA in the past. We have had numerous difficult calls from the FDA on some of the claims about the product. We, indeed, complied with those different things.

[At this point in the hearing, Senator Chiles reentered the hearing room.]

Mr. Hughes. And I would like to say nobody in this industry has stated exactly what you can say about a product. The FDA does not say "This is exactly what you say about a dietary supplement." The FTC does not have something where it says "This is exactly what you are allowed to say about dietary food supplements." The Attorney General does not have anything where it says "This is exactly what you say about a dietary food supplement."

What we have put in our literature is what we think to be true through hundreds of thousands of people who have used these products. If this committee or any other agency feels some of those claims are misleading, we will be glad to discuss it. As I told your staff before, we will be open to conversation. Not many of these conversations have taken place at this particular time. Most of the conversation has been saying we are a bad company. I don't think you can be too bad when there are over a million people who have been on these products that have helped people.

Other than that, I am here and willing to answer any questions from the subcommittee. Thank you very much.

Chairman ROTH. Dr. Katzin, I understand you have a written statement.

Dr. KATZIN. I do. I have submitted it to the Senate. I would like it entered. I have along with that my credentials and a list of the diagrams.

Do you have that in front of you? I would like to summarize my statement.

First, I would like to begin by thanking the permanent subcommittee for having this hearing and for inviting me to speak. Just to review my credentials for a moment, without taking too much time, I have an M.D. and a Ph.D. both from UCLA. My Ph.D. is in physiology with a minor in chemistry and molecular biology; M.D. degree with training in internal medicine and many years experience in the field of medicine. My practice consists of a general preventive medicine practice dealing primarily with problems of lifestyle and weight loss. I belong to many professional societies. I publish in reputable journals and I managed a laboratory for a number of years where we did cardiovascular research.

I feel I am uniquely qualified to comment on many of these issues because I see them both from a physician's—that is an individual who deals from a people's point of view and a scientist who can represent the academic side.

Over the last 5 years, I have managed probably 1,000 people, many of these with weight control related problems. As you heard both today and yesterday, obesity really is a major problem in the United States. I personally would not classify obesity as a disease. I feel rather it is a result of changing lifestyles, as Dr. Young pointed out. We have become a society that is too sedentary; there is too much access to high-caloric foods and foods that are very palatable and allows the expanding girth problem we have seen before.

However, as the Senate Select Committee on Nutrition pointed out, obesity does represent a major problem to health. It is a causal factor in many diseases and actually contributes to mortality in six of the major causes of death in this country, and they, therefore, recommend immediate attention to it.

As a physician who has dealt personally with many of these patients, let me say obesity is significant not only in the physical pattern and the way it affects disease, but also in the way it affects individuals personally, their lives, their families.

Those of us who have never had a weight problem, I don't feel, can really begin to imagine the frustration, the despair and the anguish that obesity creates. In addition, obesity drastically affects an individual's self-confidence and decreases his earning power in the marketplace. For these reasons, obese individuals desperately search for weight-loss programs. Unfortunately, few of them, even the ones medically supervised, well researched and well supervised, ever succeed.

You heard yesterday the rule quoted, approximately 80 percent of individuals who lost weight will gain that weight back and will go up and down in what has often been called the yo-yo method of girth control.

My colleagues in the medical community have been just about as unsuccessful in helping people lose weight as have lay organizations or lay people. Mr. Hughes alluded to many of the extremes to which my medical colleagues have resorted, including hormone injections, amphetamine use, jaw wiring and intestinal bypass operations, many of which have had to be abandoned because of the drastic effect they have on the body.

The dismal success of the medical community in controlling weight has led Albert Stunkard, M.D., University of Pennsylvania, to state, "The most promising new methods of controlling obesity seems to lie almost entirely outside the medical profession."

It is against this background that the Herbalife Nutritional Program was created approximately 6 years ago. Since there is so much confusion as to exactly what is the Herbalife Nutrition Program, and I feel much of the criticism comes from that, I would like to set the record straight.

Very simply, the Herbalife Nutrition Program is nothing more than a complete balanced basic nutritional program. It is a combination of macronutrients which we know as protein, carbohydrates, fat, and micronutrients, primarily vitamins and minerals that are necessary for a balance of good health.

When this combination is used along with a specified meal plan, which includes meals drawn from the seven basic food groups, a 1,000-calorie safe and effective weight reducing diet can be achieved.

The committee has heard both today and yesterday considerable testimony about the benefits and dangers of very-low-calorie diets. These are diets which contain approximately 500 calories or less. They generally consist exclusively of formula drinks. One such diet is the Cambridge diet. Other such diets include medically supervised Medifast and Optifast. These diets are potentially extremely dangerous and must, under all circumstances, be medically supervised. Even then serious side effects may occur.

However, medical supervision reduces the risk of prolonged or permanent complications.

Herbalife is not a very-low-calorie diet. Can we put up our first chart? [1] This chart is a comparison of the Herbalife program and the center column is the Optifast which is a very-low-calorie program. The distinctions are clear. The Herbalife program contains at least 1,000 calories. The Optifast contains approximately 500 calories.

In addition, you can see the breakdown of protein, carbohydrates and fats are entirely different. If you take a look at the fifth line down, potassium, the Herbalife contains approximately 2.5 grams of potassium which is about the RDA requirement for a person, whereas the Optifast contains approximately 1 gram. In fact, if Optifast and Medifast are not supplemented with potassium, dangerously low potassium levels can develop

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[1] The charts and graphs referred to throughout this testimony may be found starting on p. 262.

In addition, you can see the RDA of vitamins and minerals are not always found in the Optifast-type diets. The Herbalife program, however, contains at least the RDA of all the essential vitamins and minerals.

I must respectfully disagree with some of my esteemed colleagues who spoke yesterday when they stated a 1,200-calorie diet plan was adequate for weight loss. As you can further see in the accompanying diagram, a 1,200-calorie diet based on nutrient proportions recommended by the American Dietetic Association, which closely approximates what the average American eats at best, may lead to a deficiency in protein as well as many vitamins and minerals. Such a diet, unless supplemented with a mineral and vitamin tablet, would certainly lead to deficiencies and must be considered unsafe.

In fact, there was just today an article in the Washington Post that stated no diet plan on the market today was safe unless supplemented by such a vitamin/mineral formula.

Because of lack of supplementation in these diets, the 1,200-calorie diets have notoriously poor compliance. They are very difficult for the people to manage, because they have to buy the food, prepare the food, and must know exactly what proportions to do that in.

There were questions raised by Congressman Dannemeyer about the quality of the food because of the nutrient drain on the soil today.

Individuals naturally discontinue such diets because they lead to emotional lability and cravings, so they quickly regain their weight.

I would certainly agree, however, with my colleagues in stating that weight loss is ultimately a matter, and very simply a matter, of taking in fewer calories than you burn up. However, I think it is insensitive to think someone can just go out and do that on their own. If that were the case, there wouldn't be a weight problem in the United States today. For an individual to continue to do this over the long run, a nutrition program must be safe, must be effective and, above all, be convenient.

I believe the Herbalife nutritional program is all of these and, therefore, succeeds where so many others fail.

Let me address the issue of safety for a moment. There are several ways to determine the safety of a nutritional program. One way is to evaluate the components of the product theoretically on the basis of previous research and on that basis determine whether the product might be safe or not.

The Herbalife program clearly is safe by this standard for all the reasons noted above. The ultimate test of safety, however, and effectiveness, I might add, of a product is to test the product in the field. By this standard, Herbalife is also safe. As Mr. Hughes mentioned, literally billions of portions of this product have been served to more than a million individuals with only minimal transient side effects.

I know of no other nutritional program which has been used as widely as the Herbalife program or which can claim to be equally safe.

Now, a third way of evaluating the safety of a program such as this is through laboratory testing. A major concern in the long-term use of a program like the Herbalife one is the development of deficiencies, particularly of serum electrolytes and minerals. As part of a long-term prospective study, presently being initiated at the University of California, San Diego, we evaluated several Herbalife consumers for nutritional deficiencies. These individuals have used the Herbalife Nutritional Program for 6 months to 4 years, certainly enough time to develop nutritional deficiencies.

Complete blood profiles, including serum electrolytes and serum minerals, were obtained. As you can see in the accompanying chart, there were no deficiencies of serum potassium, magnesium, calcium, iron, zinc and copper. In fact, as the next table indicates, there were no abnormal findings in the blood of these patients whatsoever.

We evaluated approximately 35 separate items. From this, I think we may conclude the Herbalife program is nutritionally safe. Further detailed reports from clinical studies will be available within 60 to 90 days. However, I might question whether or not clinical tests are valid tests for evaluating such a program as this. The population is a controlled population. It is very carefully supervised not the way it is done in the field. It is generally a small population of 100, 200 people that is studied for a relatively short period of time—6 months to 1 year—and problems which develop in patient compliance and in terms of larger populations are never seen.

For that reason, I would only admit that kind of evidence as a partial indication of safety or effectiveness.

Let me turn to the issue of effectiveness. As part of a retrospective survey of the entire Herbalife consumer data base, the following initial results have been obtained. The accompanying graphs show the weight loss distribution in a sample of Herbalife individuals who have used the product for more than 6 months.

The total number of individuals in this study is 428. Of these, 381, or approximately 88 percent, lost weight while using the products. I would say that that is considerably more than a placebo effect of 30 percent.

The graph shows the distribution of weight loss in pounds on the bottom scale and the number of individuals in each category on the left-hand scale. If you look toward the left diagram, you will notice that more than 30 percent of the individuals in this study lost 30 pounds or more; 10 percent have lost 50 pounds or more. As you will recall from yesterday's testimony, 30 pounds represents the minimum cutoff point for obesity in an average person whose ideal weight would be 150 pounds. Obviously, the program is very effective for people who have to treat the problem of medical obesity as well as excess weight.

The question may be raised, why didn't all the individuals lose 30 pounds or more? The answer is because the individuals in this study did not need to lose that much weight. In the next graph, we see that 97 percent approximately of the individuals in this study are maintaining their weight. This period of weight maintenance has been 6 months to 2 years. Many of them are still ongoing in that process.

Clearly, the Herbalife program is effective for individuals who need to lose anywhere from 5 to 50 pounds.

None of the individuals in this group has so far regained their weight. Since as we noted above less than 10 percent of individuals who lose a significant amount of weight maintain that weight for more than 1 year, the results of this study are extremely, extremely encouraging. Clearly, the Herbalife nutritional program represents an effective weight loss control technique.

I would like to summarize my statement as follows: Obesity is a major problem in the United States today with many physical, emotional and social ramifications. The treatment of obesity is primarily a lay problem, not a medical one, and must be solidly grounded in a good nutritional program that gives the individual fewer calories than he consumes. The Herbalife nutritional program is such a program. It is safe and effective when the recommendations made by the company are followed.

The Herbalife nutritional program is a low-calorie nutritional program, one that is an alternative to complicated and potentially deficient diet plans. It is not a very-low-calorie diet and should not be confused with one. Because of this, it is safe for the vast majority of individuals who need to lose weight.

Thank you for allowing me to appear before the Senate committee. I congratulate the Senate on examining this difficult field. I have just been told by counsel I went a little fast. I can go over it a little more slowly, if you like.

Chairman ROTH. We will leave that to the questions. Mr. Hughes, so that we all understand your program, like a lot of people, I like to watch my weight and occasionally diet to try to keep it down. Why should I, if I were on such a program, take Herbalife? What are the benefits to me?

Mr. HUGHES. To lose weight.

Chairman ROTH. How does it enable me to lose weight? What does it do differently, for example, from reducing the number of calories I take?

Mr. HUGHES. Two things. One is with the program, you are taking in less calories every single day. You can say, well, listen, I can do that with lower food intakes and that would be fine to say that in theory, and some of the things we heard here yesterday, were, in fact, in theory, correct but if you could easily lose weight by taking in less food, No. 1, that would be working right now. We wouldn't have so many of the population overweight. So this is a sensible, easy way of allowing someone to take in good sound basic nutrition and eat a normal meal, which is what I did. I lost 16 pounds on the product 6 years ago and kept it off.

Chairman ROTH. Again, I am not clear in my own mind as to what your products will enable me to do that I cannot accomplish just by reducing the number of calories. What is the impact, the effect of your product that reduces my appetite——.

Mr. HUGHES [interposing]. Good nutrition. If we were to outline, as we just did here a minute ago, if we were to outline 1,200 calories in food, you can certainly see you have a nutrient deficient diet.

Chairman ROTH. I noticed in your description, you did talk about 1,200 calories. How many calories do you have in the various products that you take?

Mr. HUGHES. The way someone uses the product is they take two shakes a day to lose weight, approximately 200 calories by the time they add milk to it. Usually some add banana or some fruit which spices it up. So it is 400 calories in both the shakes and then they eat a normal meal. Sometimes that is 600 calories, sometimes that can be—it can be 1,000 calories.

My cousin has lost a significant amount of weight. To be perfectly honest with you, he probably would have lost weight on 2,500 calories a day because he was rather large.

Chairman ROTH. Do you recommend that you can take the product with just milk or juice?

Mr. HUGHES. Do we recommend the product be used with milk? Yes.

Chairman ROTH. Solely with milk or juice, or can be safely taken with just milk or juice?

Mr. HUGHES. Sure, but you have to eat; you have to eat a main meal.

Chairman ROTH. Your proposition here is they do eat at least 800 calories?

Mr. HUGHES. Sure they do. I think that was clearly already explained.

Chairman ROTH. Is that spelled out on the label in the products you sell?

Mr. HUGHES. On the label and also in the literature.

Chairman ROTH. Do you agree or is it your statement that your products are safe for all people, for all humans to take, including children and pregnant mothers?

Mr. HUGHES. Good, sound, basic nutrition everybody needs. So far, like I stated earlier, there has been 9,600,000,000 portions of the product used.

Chairman ROTH. Let me ask you, is your basic position that it is safe for everyone to take without medical review?

Mr. HUGHES. Unless someone is being fed intravenously, then everybody needs good, sound, basic nutrition; everybody needs that. I think we all know that.

Chairman ROTH. Except if it is taken intravenously, it is safe for everyone, whether they are children or people with heart disease——

Mr. HUGHES [interposing]. Up to 4 years old. There are recommendations for children which we have a product called "Kindermins."

Chairman ROTH. Do you give any kind of warning on your labels as to children?

Mr. HUGHES. For under 4, no; we do not.

Chairman ROTH. Is there any kind of warning or advice——

Mr. HUGHES [interposing]. No, but I think we also ought to note this: We don't sell it to 4-year-olds. Obviously, it would be the parents' responsibility if they were to allow one of their children to use the product.

Chairman ROTH. But is any warning given to those parents that the product should not be given to small children?

Mr. HUGHES. Sure; that is why we have specific products for children.

Chairman ROTH. But is it on the label?

Mr. HUGHES. No.

Chairman ROTH. I noticed in the written testimony of Dr. Katzin, the statement is made on page 8, "It is not a very-low-calorie diet and should not be confused with one. Because of this, it is safe for the vast majority of individuals who need to lose weight."

By inference, while it is safe for the vast majority, there must be certain individuals for whom it is not safe. Is that an accurate statement?

Mr. HUGHES. Everybody needs good, sound, basic nutrition, period. [Laughter.]

Chairman ROTH. That is not my question. My question, Mr. Hughes, is that in the prepared statement of your expert, the conclusion is drawn that because of this, it is safe for the vast majority—vast majority—of individuals who need to lose weight. By inference or implication, there are some whom it is not safe for; is that a correct statement?

Mr. HUGHES. If you want to know my opinion on it, is it safe for people and for human consumption, the answer is yes. If you want to know if there is someone who should not use it, you will have to ask Dr. Katzin that question.

Chairman ROTH. As I understand, Dr. Katzin is here as your expert in this area. I will ask him, what do you mean——

Dr. KATZIN [interposing]. What I meant by that, Senator Roth, there are a certain number of individuals who are under their doctor's care and have special dietary requirements as prescribed by their doctor and are not in the market for weight loss. These would be individuals on dialysis, who may have particular problems with intravenous feeding, intestinal bypass operations, and so on, and must restrict their food to a completely institutionalized or physician-recommended program. Those people are completely under their doctor's care, of course, and would not be using this product, and I don't know that I would recommend it for them. For the vast majority of people who are walking around today and need to lose weight, this product is safe.

Chairman ROTH. Do you think this is safe for all pregnant women?

Dr. KATZIN. The product is safe for pregnant women. I personally would not recommend weight loss for a pregnant woman unless she were under a doctor's supervision and told to do so. Were she told to do so by her physician, this would be a safe, effective way to do that.

Chairman ROTH. Wouldn't it be appropriate then for the label to give that warning so that the typical pregnant woman would have some warning that she ought to check with her doctor?

Dr. KATZIN. Well, I think the typical pregnant woman in this country is under the supervision of her doctor who makes dietary recommendations to her. You are dealing with a labeling issue, Senator, and I am afraid I don't know about labeling issues. I do know about medicine and I do know pregnant women are under the control of their doctors.

Chairman ROTH. Doctor, you said yourself that you would not advise a pregnant woman to take it without——

Dr. KATZIN [interposing]. I didn't say that. I said I wouldn't necessarily recommend that a pregnant woman lose weight. These are actually nutritional supplements which may be used in conjunction with more than——

Chairman **Roth** [interposing]. As a doctor, wouldn't you want pregnant women to be advised that is is not wise for them to lose weight?

Dr. **Katzin**. I don't necessarily—I guess I would have to throw that back to you; is that the responsibility of——

Chairman **Roth** [interposing]. I am asking you.

Dr. **Katzin**. Of any product in the weight-loss market or any other market to advise a pregnant woman she should not lose weight unless told by her physician, I would have to take that under consideration because there are implications to that.

If you advise a pregnant woman, would you advise other people, and so forth, so on.

Chairman **Roth**. Let me ask you a question. Why shouldn't a pregnant woman lose weight? What are the consequences of doing so?

Dr. **Katzin**. Unless a pregnant woman is extremely overweight she should not lose weight. There is also a problem called toxemia in pregnant women which is associated with obese women though not exclusively. In general, because the fetus is growing inside her, it is recommended that she gain weight. Now, very often one of the problems with pregnancy is nutritional inadequacy. This comes up in two general areas. Nutritional inadequacy of vitamins and minerals and nutritional inadequacy of protein. Unless the pregnant woman is on an excellent diet and under the supervision of a good dietician and physician, I would certainly recommend the use of some of these products in addition to her regular diet to assure adequate intake of protein and vitamin/mineral supplementation.

I would not recommend that any pregnant woman lose weight unless, as I said, told to do so by her physician. Is that clear?

Chairman **Roth**. I think it is an important point that it is not wise, in your medical expertise, for a pregnant woman to try to reduce weight unless under a doctor's care.

Dr. **Katzin**. I certainly would agree with that.

Chairman **Roth**. You also say at least children, maybe it was you, Mr. Hughes, young children under the age of 4 should not be given such products for the purpose of reducing weight; is that correct?

Dr. **Katzin**. Well, once again, I am not one who believes that children should generally be on weight-loss programs. It is a very controversial issue. When you start to get to the age of adolescence, it becomes more controversial. Children should be under the guidance of their parents and the family physician in these matters.

Chairman **Roth**. Mr. Hughes, do you think that a product, such as you sell, should be labeled so that anyone who may be adversely impacted is warned as to the effects of taking those products? Do you think it is in the interest of good public policy that pregnant women be warned they should not try to reduce without a doctor's assistance and advice?

Mr. **Hughes**. I don't think there are any women that are pregnant that aren't seeing their doctor.

Chairman **Roth**. That is not really the question. They may or may not. My question, again, is shouldn't they be put on notice that they should discuss this matter with a doctor—yes, you are right, they, of course, are seeing the doctor probably for purposes of delivery and having the baby, but shouldn't there be some notice given to mothers, prospective mothers throughout the country that before they take these products that they ought to consult with their doctor? What is wrong with that?

Mr. HUGHES. Oh, nothing is wrong with it.

Chairman ROTH. Why shouldn't it be done?

Mr. HUGHES. It should be done; it can be done, but I think all people should have the inherent right to consume good, sound, basic nutrition. I think all people should have that right. If they want to see their physician, I think that's great. There's nothing wrong with that.

Chairman ROTH. What I am going to is the testimony by your expert who says it is safe for the vast majority but by inference states that for others, it raises a health problem. He states that it is a question as to whether or not pregnant women, children, those under other medical treatment, wouldn't it be wise for your products to give some kind of warning or notice that in the event you are one of those individuals that you should consult with a doctor before you take the product?

Mr. HUGHES. If the question here is whether we are opposed to putting it on there, we are not opposed to it. We are certainly open as a company to listen to any particular advice.

Do I think it is necessary for anybody to obtain a doctor's permission to use good, sound, basic nutrition? Absolutely not, no more so than it is for you to get a chemical breakdown any time someone eats a hamburger.

Chairman ROTH. My time is up. Senator Rudman.

Senator RUDMAN. Thank you very much, Mr. Chairman.

Dr. Katzin, Mr. Hughes, I have a series of questions for you. I will try to make them brief. I would appreciate brief answers. Dr. Katzin, when did you go on the payroll of this company?

Dr. KATZIN. I am not on the payroll of this company, sir. I am a consulting physician who has been engaged to do research with this company——

Senator RUDMAN [interposing]. When?

Dr. KATZIN. This began approximately 3 months ago.

Senator RUDMAN. As a matter of fact, the lawyers, in a meeting with our staff, said you were hired in part because of this committee's investigation; is that correct?

Dr. KATZIN. I was hired before there was any knowledge, to my understanding, of this committee's investigation.

Senator RUDMAN. You are not one of the original founders of the company?

Dr. KATZIN. No, I am not.

Senator RUDMAN. And you had nothing to do with the formulation of the product?

Dr. KATZIN. No, I did not.

Senator RUDMAN. Thank you. Mr. Hughes, Dr. Marconi—do you know where he is today?

Mr. HUGHES. Yes, I do. He's in China.

Senator RUDMAN. Where is he?

Mr. HUGHES. In China.

Senator **Rudman**. You know we have been trying to get him to the hearing for 2 months; right?

Mr. **Hughes**. I hope I am allowed to answer the question.

Senator **Rudman**. You said China. Does he know about the hearing?

Mr. **Hughes**. He does now; yes.

Senator **Rudman**. Did he know we were going to have the hearing?

Mr. **Hughes**. At what time?

Senator **Rudman**. April 23.

Mr. **Hughes**. April 23?

Senator **Rudman**. Yes.

Mr. **Hughes**. He did not know whether he was going to be here or not; let me tell you why.

Senator **Rudman**. When did he decide to go to China, Mr. Hughes? Now you can answer that.

Mr. **Hughes**. OK.

Senator **Rudman**. When?

Mr. **Hughes**. I'm sorry?

Senator **Rudman**. When did he decide to go to China?

Mr. **Hughes**. Last year.

Senator **Rudman**. And he decided last year that he would go this week?

Mr. **Hughes**. Yes; can I answer the rest of the question?

Senator **Rudman**. Sure; go ahead.

Mr. **Hughes**. Mr. Marconi did not know when this hearing was going to be because we volunteered to come to a voluntary meeting—Mr. Rinzel, Mr. Shapiro—and at that meeting I brought three of the doctors. I, at my own expense, sat through 5 hours of dissertation, and at that time, we were told before we got there that Herbalife needed to come into that meeting because we might not be subject to a hearing, that there might not need to be a hearing as a result of us coming and telling some of the things, and that they did not know when the hearing was going to be scheduled because Senator Roth was possibly going to go out of the country.

Senator **Rudman**. That is enough explanation. I accept your answer. Your answer is he didn't know. I believe you. I am not challenging you on that. I accept that.

Dr. Marconi is called Dr. Marconi. Dr. Marconi got his degree last year from a place called Donsbach University. I have checked it; it is a totally unaccredited mail order university and he did not attend the appropriate classes you would normally expect to get a Ph.D. Do you know about that yourself?

Mr. **Hughes**. Dr. Marconi is one of the most brilliant guys I know.

Senator **Rudman**. I didn't ask you that. This is a direct question. This is not a sales pitch. A very direct examination. I am not going to harass you. I accept your answers. I simply ask you, Mr. Hughes, whether or not you knew that this doctorate this man allegedly has is from a totally unaccredited university, well known in California in the Attorney General's office as an unaccredited university? Not this fellow here, Dr. Katzin who has very good credentials that came on board 3 months ago, but Marconi who has been there since the beginning, he, in fact, is really not a Ph.D. in nutrition; do you know that?

Mr. HUGHES. I don't know about that. I don't know of any Attorney General, Donsbach.

Senator RUDMAN. You don't know about Donsbach?

Mr. HUGHES. I know about Donsbach. I don't know about the problems you talk about.

Senator RUDMAN. Let's talk about something you do know. You say you are an expert in this field; you are an authority, to use your words. My understanding is you have no college degree?

Mr. HUGHES. Accurate.

Senator RUDMAN. My understanding is you completed the 9th grade in school?

Mr. HUGHES. Accurate.

Senator RUDMAN. In spite of that, you want this committee to accept you as opposed to the witnesses yesterday and Dr. Katzin as an authority?

Mr. HUGHES. I defy anybody in this room that has submitted what they know about people losing weight so far to be able to produce results as this company has. I don't know if some of the physicians yesterday have seen literally millions of people, helped them lose weight—I don't know. I seriously doubt it.

Senator RUDMAN. You are the founder of this company?

Mr. HUGHES. Yes, I am.

Senator RUDMAN. And you are the chief executive officer?

Mr. HUGHES. Yes, I am.

Senator RUDMAN. And you are responsible for the management of this company since the beginning; correct?

Mr. HUGHES. Yes, I am.

Senator RUDMAN. Let's talk about your career book, which is no longer in use. Let's talk about it. The career book says, amongst other things—this is a very good copy. It is part of the original from your career book. Chickweed is good and helps asthma, bronchitis, cancer, hemorrhoids. Gotu kola is good for age spots, senility, memory, and menopause. It says that burdock root is helpful with gallbladder, gout, ulcers, and venereal disease. Dandelion is helpful with diabetes, eczema, insomnia—I won't bore you, Mr. Hughes. You wrote it or someone who works for you wrote it. Did you approve that?

Mr. HUGHES. No; we did not write that. Authors, scientists, and doctors wrote that information.

Senator RUDMAN. You published it.

Mr. HUGHES. Can I finish?

Senator RUDMAN. Just answer if you published it, then you can finish.

Mr. HUGHES. We did not write that. All the books have been listed in which the material came out of it. It was listed on D-30, if I am not mistaken.

Senator RUDMAN. I have it. But you published it?

Mr. HUGHES. You specifically can see what is claimed in there; Herbalife made no such claims. The reason the other material was in there is because I was under the opinion then and under the opinion now that if I was to pull anything out of its entire context and put it into our manual, I could be sued for taking it out of its entire context.

The claims Herbalife made were on whole pages, and said that Herbalife could typically help someone with their appetite. There were things in there that said it is effective in appetite, effective in cleansing, effective with different things and I only wanted people to believe that. None of the other things were meant for someone to believe that the product would do those things, otherwise I would have put it in the direct bullet.

Senator RUDMAN. Back to my basic question. Aside from how you got it, you took this information, including, by the way, a very eminent journal, Ceylon Daily News of December 22, 1932, an article appearing, "Gotu Kola: The Secret of Perpetual Use." That is one of these sources. You took this information, you didn't write it, you took it and you published it, true or false? You published it; you paid for the career book being printed; correct? Simple answer.

Mr. HUGHES. Certainly we did.

Senator RUDMAN. Thank you. Now I want to talk about your endorsements. You have people appearing as recently as last night at your rally that come up on your cable program and ascribe all kinds of things to this product other than weight loss. I am not interested in talking about weight loss because maybe it works; I won't even challenge you on that.

Mr. HUGHES. You say you won't challenge us on weight?

Senator RUDMAN. I don't think so. I happen to think if you drink water, you lose weight, and it is free. At least where I come from it is free. [Laughter.] I simply ask you whether or not last night you did not have a testimonial from someone who came up on your show and said I have diabetes; I took this marvelous product and now I am cured; is that true?

Mr. HUGHES. It was not aired on television.

Senator RUDMAN. It has been aired on television.

Mr. HUGHES. No.

Senator RUDMAN. I have one——

Mr. HUGHES [interposing]. I would love for you to show it to me. Specifically not in any of our cable broadcasts.

Senator RUDMAN. Let me ask the question carefully because you are under oath. On the cable programs that you run, do you have people that appear on those——

Mr. HUGHES [interposing]. We do not have people appear on them—people that are there.

Senator RUDMAN. People that are there in the studio audience, part of the group, who stand up on their own free will—I am not accusing you of anything, Mr. Hughes—own free will and say that these products, and there are a whole bunch of these products, not just the diet products, these products have had a change in their health other than weight loss.

Mr. HUGHES. Do we have someone say that?

Senator RUDMAN. I didn't ask you if you had someone say that. I ask if someone says this on these programs that you pay for.

Mr. HUGHES. The answer is no.

Senator RUDMAN. You are sure of that?

Mr. HUGHES. I would love for you to produce such evidence. We specifically take those tapes and we edit them before they ever air.

Senator **Rudman**. And you are telling me—asking you one more time—none of these cable programs contain anyone making representations about health cures of these products other than weight loss?

Mr. **Hughes**. There only were two live shows that this company ever aired. After those two live shows, we did not think that it was accurate to air the live shows any longer, and we edited everything in those television cable shows.

Senator **Rudman**. No, in fact——

Mr. **Hughes** [interposing]. Except for weight loss; excuse me.

Senator **Rudman**. In fact, your distributors who are customers of yours, even though you no longer print these claims from all of these marvelous journals, like the Ceylon Daily News of December 1932, they have all these booklets in which they tell these salesmen a whole list of things in here that are remarkably similar to what you put in your career book back in 1982; are you aware of that?

Mr. **Hughes**. No; I'm not.

Senator **Rudman**. You are not aware of that?

Mr. **Hughes**. I am aware of that booklet because it was given to Mr. Rinzel.

Senator **Rudman**. You mean your company supervises your distributors so little that you don't even look at the literature they are publishing to sell a product that you are responsible for?

Mr. **Hughes**. If this company ever finds anybody publishing other than what they can purchase at the warehouse which is published by Herbalife, they are sent a letter from our legal department that says they have committed the following problems within the company. At that time, they are suspended from buying any product from this company. They are suspended from being able to get any bonuses from this company. After that person signs a statement which says that they have done something improper, such as publish the piece of information that you have there. If they haven't signed the statement within 15 days, they are terminated from the company.

Senator **Rudman**. How many have you terminated?

Mr. **Hughes**. 358.

Senator **Rudman**. Would you supply a list of those for the record?

Mr. **Hughes**. Yes; I would and they are in different categories, by the way, also. Some are people that have misadvertised the product. Some are people that have specifically not given a refund. There is a 30-day money back guarantee on these products regardless of whether they don't like the look of it, smell of it, anything else, even if they don't like the labels. There have also been people who have not done things accurately in the marketing plan. Indeed, this company terminated one person even when they were making $30,000 a month. It is not predicated on whether someone is making money with us. We are interested in making certain everything is done accurately.

Senator **Rudman**. When the list is received it will be marked as exhibit No. 16.

[Exhibit No. 16 may be found in the files of the subcommittee.]

Senator **Rudman**. Mr. Hughes, would it be fair to say those people suspended based on your own records and what this committee was told, many were suspended for a number of reasons, many of which were not the reasons I asked about; is that an accurate statement?

Mr. HUGHES. Three of the situations I just quoted to you——

Senator RUDMAN [interposing]. I am talking of the 350. Many were suspended for reasons that have things to do with other matters other than false representations?

Mr. HUGHES. They have been terminated for false representation, for advertising——

Senator RUDMAN [interposing]. Only?

Mr. HUGHES. No; I don't know how to say it any clearer. I said three different categories.

Senator RUDMAN. Well, we will put in the record why they were suspended.

Finally, let me simply ask you, all of these claims that you publish because you thought the people had a right to know about them, the things about cancer cure, diabetes, and so forth, which you simply took from other places around the world that I have quoted and I won't quote them all, and you published them in your career book; you paid for it, sent it out around the country to all your folks. Did you believe the claims in here yourself?

Mr. HUGHES. The ones specifically Herbalife made which is on the official page, absolutely I do, and there are hundreds of thousands of people——

Senator RUDMAN [interposing]. I am not talking about those, all of these others that other people wrote.

Mr. HUGHES. I have already stated as to appetite and certain things that Herbalife claims, those are the things I believe which is the reason why it was put in. The other things, I don't know if it does that or not. We did not ever want to make claims for the other things because of the fact that we have hundreds of thousands of people who have lost weight with the claims we have made about the product.

Senator RUDMAN. But because some quack someplace said a particular herb might cure cancer, you felt that you were OK to represent to the people across this country that that might cure cancer; you thought that was all right as a responsible businessman; you thought the public ought to know no matter who said it; is that your attitude?

Mr. HUGHES. Absolutely not.

Senator RUDMAN. Then why did you print it?

Mr. HUGHES. Because I wanted to show the efficacy of what we were saying and that is why they were taken out. I did not think we were allowed to take anything out of its entire context. Indeed, if you were to look up those things they were taken out of the entire claims. Two of the things were made about our products—appetite and so on, period.

Senator RUDMAN. Mr. Hughes, I am probably out of time.

Let me simply say, frankly, that is one of the most incredulous explanations I have ever heard from anybody trying to sell even snake oil. And I want to ask you a question, Doctor. How much are you getting paid?

[At this point in the hearing, Senator Gore reentered the hearing room.]

Dr. **Katzin**. I get paid by the day for each day that I am with the company on a journey such as this or for working such as this. I get paid what I actually bill each day in my practice. I will discuss it if you wish.

Senator **Rudman**. You can discuss it now if I wanted to press it. I won't. That is private information. The fact is, you came on board here about 3 months ago.

Dr. **Katzin**. Let me explain something about that.

Senator **Rudman**. It is a simple question, doctor. I don't need explanations. This is not a forum for you to give a lecture to me; this is a forum for me to get information. I have a simple question for you doctor. You have been here by your own testimony about 3 months. You were hired to come to this hearing; is that true or false? That is a simple question, Doctor.

Dr. **Katzin**. It is a simple question. It is quite a tone you are using to ask a simple question. The answer to that "simple question" and to that tone is "Yes."

Senator **Rudman**. Thank you. Because I think that tells us a lot of why you are here.

Dr. **Katzin**. No, I don't think it does, Senator Rudman, and I would like a moment to address that issue. I have a very successful practice, and I do a lot of consulting. I work with a number of organizations on nutritional problems. I work with a repair organization which is for alcoholic abuse, a detox program, and so forth. I do nutritional consulting for all that at no cost. I do a lot of work with the public, exactly because of the attitude I see here in the Senate; there is a lot of railroading going on in this issue. There is a tremendous story out there of which this is just the tip of the iceberg in terms of safety and effectiveness of a product which helps people lose weight. Other weight loss treatments and plans have been a disaster in the medical and the social marketplace and costs billions in quack medicine. I didn't feel the gentlemen here were being given a fair chance, and I am not sure that I do today, given your attitude. I certainly don't see it treated fairly in the press. That is why I got involved. Certainly not for the money.

Senator **Rudman**. You certainly don't approve of the articles they publish in their career book, Doctor? Had you been there at the time, you would have advised them not to publish those things, wouldn't you?

Dr. **Katzin**. I would make different recommendations.

Senator **Rudman**. I would think you probably would.

Dr. **Katzin**. And now I am on board.

Chairman **Roth**. I think we will recess to go vote. Senator Cohen?

Senator **Cohen**. Just a couple questions, Mr. Chairman. Mr. Hughes, who manufactures Herbalife?

Mr. **Hughes**. D&F Industries in Orange, CA.

Senator **Cohen**. What is D&F?

Mr. **Hughes**. D&F is the largest manufacturer of food supplements in the world.

Senator **Cohen**. Who runs D&F?

Mr. **Hughes**. Dick Marconi and Fred Siegel.

Senator **Cohen**. Is this Dick Marconi the same Dr. Marconi?

Mr. **Hughes**. Yes.

Senator COHEN. Who is Fred Siegel?

Mr. HUGHES. Fred Siegel is his partner.

Senator COHEN. Is he in China, too?

Mr. HUGHES. No; he's not. [Laughter.]

Senator COHEN. How did you come into contact with Mr. Marconi? He was "Mr.", I assume, before he got his doctorate degree?

Mr. HUGHES. Yes.

Senator COHEN. How did you come into contact with him?

Mr. HUGHES. He was manufacturing the product in another company I was involved in.

Senator COHEN. What kind of product?

Mr. HUGHES. Similar to ours—protein powder, it also had vitamins, minerals, and fatty acids.

Senator COHEN. What was the name of the product that he was marketing?

Mr. HUGHES. Seyforth Laboratories.

Senator COHEN. Seyforth Laboratories. And you went to him with what, a proposal?

Mr. HUGHES. Yes. I had gotten very, very interested in developing my own business that I thought would be good and safe for people to use and also for distributors to be able to have a place where they could sell products and not get ripped off, and I went to him basically with the idea.

Senator COHEN. How old were you then?

Mr. HUGHES. Twenty-three years old.

Senator COHEN. And you went to him with this new product?

Mr. HUGHES. I went to him with the idea.

Senator COHEN. The concept; he had the product.

Mr. HUGHES. I went to him with the idea and the concept of the product; he is the one who actually developed it.

Senator COHEN. Was there ever any clinical testing done on Herbalife?

Mr. HUGHES. Sure. Dr. Katzin just showed you and each of the——

Senator COHEN [interposing]. You have done clinical testing for Herbalife?

Mr. HUGHES. Yes; on each of the ingredients there is a tremendous amount of testing.

Senator COHEN. Who does it?

Mr. HUGHES. Different doctors and authorities.

Senator COHEN. Is it Dr. Marconi?

Mr. HUGHES. No.

Senator COHEN. He didn't test it?

Mr. HUGHES. They have already been tested. There is miles of information——

Senator COHEN [interposing]. Different name; same product he was marketing?

Mr. HUGHES. Slightly different.

Senator GORE. Would the Senator yield? These tests that you say have been done, have they been done just in the last few months?

Mr. HUGHES. No.

Senator GORE. You did clinical tests before?

Mr. HUGHES. Tests on each one of the ingredients——

Senator GORE [interposing]. Clinical tests, animal studies, et cetera?

Mr. HUGHES. Yes; we would like to submit it for the record.

Senator GORE. I think they ought to be part of the record.

Chairman ROTH. Yes, if we could secure a list of the clinical tests, by whom and copies of them.

Mr. HUGHES. OK. Thank you very much for allowing us to do that.

Chairman ROTH. These submissions will be marked exhibit No. 17.

[Exhibit No. 17 may be found in the files of the subcommittee.]

Senator COHEN. Dr. Katzin, you indicated in answer to a question that you are concerned about safety. Let me ask you, Mr. Hughes, about mandrake and poke root. They were removed from formula 2, as I understand it, following a notice of adverse findings from the FDA since they were considered to be toxins; is that right?

Mr. HUGHES. That's right.

Senator COHEN. Why were they included in the first place?

Mr. HUGHES. We didn't find them then to be toxic, and we don't find them to be toxic now in the levels they are in the product. We voluntarily on the letter from the FDA took them out.

Senator COHEN. FDA found them to be toxic, but you said No. 1, you disagree with the FDA, and No. 2, you had them in such amounts it didn't matter.

Mr. HUGHES. In the levels that were present in the products, I do not believe they were toxic.

Senator COHEN. But you took them out?

Mr. HUGHES. The FDA said that earlier today, I believe.

Senator COHEN. Has Herbalife ever made any effort to recall these bottles containing the toxins?

Mr. HUGHES. Absolutely not because they don't last very long.

Senator COHEN. In a recent letter Herbalife published, you stated that none of the herbs found in Herbalife are unsafe and that most of the herbs have been used without adverse effect for hundreds of years. Were you here yesterday when Dr. Tyler told the committee the herbs comfrey and chaparral were unsafe?

Mr. HUGHES. I believe FDA said that. They said they were perfectly safe.

Senator COHEN. In the same letter, you claim cellulite is unsightly body fat. Again, yesterday three panelists informed the committee there is no difference between cellulite and other fat. How does your product Cell-U-Loss——

Mr. HUGHES [interposing]. Cellulite is the term we use to describe the way it looks. Someone said yesterday that is a coined phrase from the 1970's. Cellulite is a pumpy, rippley fat. Obviously, it is fat. It is a little more distinguishable to call it cellulite.

Senator COHEN. How does your product Cell-U-Loss eliminate it?

Mr. HUGHES. I defer to Dr. Katzin.

Senator COHEN. I want to ask you; you are the nutritional expert.

Mr. HUGHES. No, I never said that I was a nutritionist. I never said I was a doctor.

Senator COHEN. I think you said you were an authority——

Mr. HUGHES [interposing]. Authority on helping——

Senator COHEN [interposing]. Authority on nutrition because you were thin.

Mr. HUGHES. Authority on helping people lose weight. Let's not get it mixed up.

Senator COHEN. I am not getting mixed up. You were critical of the people who testified, because they were fat; therefore, what made them experts on nutrition. Did you say that?

Mr. HUGHES. On them——

Senator COHEN [interposing]. Did you say that about them?

Mr. HUGHES. On them, yes.

Senator COHEN. The next statement you made was that you consider yourself to be an authority, because you were the thin one. What does that mean?

Mr. HUGHES. As far as I know, do you know anybody else who is helping more people lose weight than me?

Senator COHEN. So that makes you an authority because you market this product?

Mr. HUGHES. I think I am an authority because I help more people.

Senator COHEN. Answer the question. I asked you about Cell-U-Loss. How does it produce a loss of cellulite?

Mr. HUGHES. I defer to that; again, I am not a nutritionist, not a doctor and——

Senator COHEN [interposing]. You are not an authority.

Mr. HUGHES. I am an authority on helping people lose weight.

Senator COHEN. What about selenium in your product? Do you have any concern about the amounts of selenium in your products?

Mr. HUGHES. No, I do not.

Senator COHEN. Are you aware of any testimony received concerning potential dangers of selenium in Herbalife products?

Mr. HUGHES. No. I think it is clear from the FDA today they are not concerned either.

Senator COHEN. I have a couple other questions on distributors. What does it take to be a distributor of your product?

Mr. HUGHES. They get a distributor kit which contains a manual, some of the products, roughly about $50 worth of product and literature in there and they receive that for $29.95, which is totally refundable within 90 days.

Senator COHEN. Do you give them any training?

Mr. HUGHES. Do we have training? Absolutely. There is a career book that explains explicitly upon becoming a distributor all the rules and regulations, what they are allowed to say about the product, what they are not allowed to say. We also do training on cable television; we also have training tapes available. We have cassettes available on the training, and we do distributor training all across the country.

Senator COHEN. Have you had any of your purchasers complain about the products?

Mr. HUGHES. Yes, we have.

Senator COHEN. What do your distributors do when they get complaints about this?

Mr. HUGHES. Most of the time it results in a refund.

Senator COHEN. No. I didn't mean that. I mean the people who are using the product. Have you had complaints made in terms of reactions by people who use your products?

Mr. HUGHES. There have been transient complaints, yes. Some slight diarrhea, some constipation and some headaches, which are very transient. Usually last about a week. If you take note in the beginning here——

Dr. KATZIN [interposing]. We have some of that on a graph if you would like to see it.

Mr. HUGHES. We have exact studies that have been done on that.

Senator COHEN. Who conducted the studies? Did you, Doctor?

Dr. KATZIN. It is part of the retrospective study we are conducting right now.

Senator COHEN. But you conducted the study?

Dr. KATZIN. Yes, I did.

Senator COHEN. Do you have your distributors give any advice about this product to people who are having adverse or bad reaction to it?

Mr. HUGHES. Not to continue the product, if it is something that stays with them for a considerable period of time; yes, they need to see a doctor.

Senator COHEN. What is the timeframe, about a week?

Mr. HUGHES. A week, yes.

Senator COHEN. Are you aware of an article by Dr. Stanley Bass regarding the cleansing of toxins upon a change of diet?

Mr. HUGHES. Yes, I am.

Senator COHEN. Is that distributed by Herbalife?

Mr. HUGHES. No, it is not.

Senator COHEN. Did you ever use this article when selling weight reduction products in another company?

Mr. HUGHES. No, I did not.

Senator COHEN. Did you ever work for Slender Now?

Mr. HUGHES. Yes; that was Seyforth Laboratories.

Senator COHEN. Seyforth Laboratories is Slender Now?

Mr. HUGHES. Seyforth Laboratories is the parent company. Slender Now was the product.

Senator COHEN. You used that article when you were a distributor then?

Mr. HUGHES. No, I did not.

Senator COHEN. Had you advised any Herbalife distributors about the existence of this article?

Mr. HUGHES. Yes; 3 years ago.

Senator COHEN. Have they been distributed, to your knowledge?

Mr. HUGHES. I did see it in the book that Mr. Rinzel had that was shown yesterday in testimony.

Senator COHEN. Are you familiar with Dr. Stanley Bass' background?

Mr. HUGHES. No, I am not.

Senator COHEN. Would that be one of the articles that you would advise your distributors not to distribute?

Mr. HUGHES. If they want to see that article, no, I don't see anything wrong with it.

Senator COHEN. Well, for the record, Dr. Stanley Bass is a chiropractor. I wonder what that has to do with weight reduction?

Mr. HUGHES. You just said it was an article. I don't see there is anything wrong with anybody reading anything.

Senator COHEN. Expert testimony yesterday indicated many of the herbs in your products are diuretics or laxatives. Do you agree with that?

Mr. HUGHES. Well, I think Dr. Katzin can handle that very well, especially——

Senator COHEN [interposing]. You were here yesterday. Do you disagree with that?

Mr. HUGHES. Absolutely.

Senator COHEN. They are not diuretics and not laxatives?

Mr. HUGHES. I agree based on what one of the doctors said within the 2,000 miligram category; yes, it possibly could be a laxative; yes. But that is certainly not prevalent here.

[At this point in the hearing, Senators Roth and Gore withdrew from the hearing room.]

Senator COHEN. We are going to recess for a period of 10 minutes to go and vote. The committee will stand in recess until that time.

[Brief recess.]

[Senators present at the time of recess: Senators Rudman and Cohen. Senators present at the reconvening of the hearing: Senators Roth and Rudman.]

Chairman ROTH. The subcommittee will be in order.

Mr. Hughes, let me, if I may, ask you some questions. How many people are taking your program or buying your product over the period of 5 years?

Mr. HUGHES. There's been 9,600,000,000 portions of the products used.

Chairman ROTH. And how many did you say have brought suit against you?

Mr. HUGHES. I'm told eight or nine.

Chairman ROTH. Have you received many complaints about side effects of taking the Herbalife product?

Mr. HUGHES. A certain percentage of the people do have some transient side effects; yes.

Chairman ROTH. What percentage of those do you say are having that side effect?

Mr. HUGHES. It would be better for Dr. Katzin to answer that since he did his study specifically on that.

Chairman ROTH. I will ask him. Do you have any idea yourself since he has only been with your organization, as I understand it, 3 months?

Mr. HUGHES. Roughly 10 percent.

Chairman ROTH. Roughly 10 percent.

Mr. HUGHES. Ten, 15 percent.

Chairman ROTH. Ten, 15 percent have side effects. What are the problems of these people who have such a negative reaction?

Mr. HUGHES. Transient diarrhea, headaches, mostly due to a change in the diet.

Chairman ROTH. Do you warn those who buy your product that this is a possible effect?

Mr. HUGHES. Yes, some of the people do.

Chairman ROTH. Is that on your label?

Mr. HUGHES. No it is not.

Chairman ROTH. How do you warn them then?

Mr. HUGHES. Basically by word of mouth. It is something that is very well known.

Chairman ROTH. If you sell several billion, how can you be certain that problem is understood by the public throughout the country?

Mr. HUGHES. Basically from people we hear back in the Distributor Relations Department as far as complaints on the products.

Chairman ROTH. What do you tell your distributors to tell them?

Mr. HUGHES. To continue to use the product if it is transient. If it lasts for a prolonged period of time, they should consult with their physician.

Chairman ROTH. When should they consult with their physician?

Mr. HUGHES. I would say roughly a week.

Chairman ROTH. But you rely on word of mouth principally as a means of warning——

Mr. HUGHES [interposing]. Yes, primarily because a number of our distributors have had some of those effects which have gone away within 1 week or 2 weeks, as Dr. Katzin can tell you from the studies he has done.

Chairman ROTH. I think there was testimony yesterday, and I think by respected scientists—you may not agree with them—those who are nutrition experts involved in the field that there are different categories of people that can suffer ill effects if they don't have a proper nutritional diet. Knowing that 10 to 15 percent may suffer adversely, as you indicated, don't you think that there should be a warning to those individuals when they buy the product?

Mr. HUGHES. No; because it's basically a change in diet. If someone were to go on, let's say they were eating a lot of meat, Coca-Colas and coffee and then they were to switch to an all-vegetarian diet, they would experience many of the same things as a result of their just changing diets.

Chairman ROTH. Mr. Hughes, there are experts who say that if you don't have an adequate diet, for example, a pregnant woman, it could have a serious effect on either her health or that of the baby.

Mr. HUGHES. This company, out of almost 10 billion portions consumed, has never had a lawsuit against anything that you are trying to talk to me about.

Chairman ROTH. Let me ask you again, if only one person suffers adversely, would you agree with me that is a serious matter?

Mr. HUGHES. If it was due to our product, yes, I would say it was.

[At this point in the hearing, Senator Gore reentered the hearing room.]

Mr. HUGHES. If it was proven that it was due to our product.

Chairman ROTH. There is a body of thought that an improper diet can adversely affect the health of either the mother or the child. You say you have made clinical tests. Have you made any clinical tests to determine the effect of your product on a pregnant woman?

Mr. HUGHES. No; we have not.

Chairman ROTH. Have not. How about the effect on a young child? We had, again, testimony yesterday that young people without proper diet could have their health adversely affected. Have you made any tests, clinical tests again to test the effect of the impact of your product on children?

Mr. HUGHES. Clinically, no. We have had a number of children use it and pregnant women use it, but clinical tests, no.

Chairman ROTH. Doctor, let me ask, if I may——

Dr. KATZIN [interposing]. Senator, I wonder if I might address that last question very briefly? There seems to be a sense in the use of the word "product" that makes it sound like a drug or a chemical or something that one must test or look into This is actually a program, each of the components of which is some kind of food or food concentrate.

Chairman ROTH. I think, Doctor, the word "product" is fairly neutral. But let me go on to make sure I understand the charts attached to your study. As part of your study, you have duration of side effects.

Dr. KATZIN. Yes; and that is the percentage of individuals and the duration in terms of weeks; the percentage along the left-hand scale and the weeks along the bottom. We have that for the cameras, if you need to bring them out.

Chairman ROTH. Do you have the enlarged chart? [1]

Dr. KATZIN. Yes, we do.

Chairman ROTH. Would you bring it up, please.

Let me ask you, this chart is based on what kind of study?

Dr. KATZIN. This is a retrospective survey. It is a survey done—it's the same basic group of individuals in the study previously that we have the historical information on. There were 175 individuals in this group.

Chairman ROTH. There were 175 in this group. When was this study made?

Dr. KATZIN. This was a recent study that was done to compile data on this program. This has been going on for approximately 2 to 3 months.

Chairman ROTH. What is the 70.9?

Dr. KATZIN. 70.9 indicates the number of individuals for whom the duration of the side effects was 1 week or less. In other words, we polled a number of people and asked them, did you have side effects? Yes. How long did they last? They fill out 1, 2, 3, 4 weeks, so forth.

Chairman ROTH. What percentage of that group did have——

Dr. KATZIN [interposing]. That is 70 percent of that group. Of the total group, 128 people were polled—it is approximately half—it is about 35 percent.

Chairman ROTH. Then the next figure you have, 16.6?

Dr. KATZIN. And that was the number of people who had side effects, the number that had actually lasted more than 1 week, in the 1 to 2 week range, by their report.

Chairman ROTH. What percentage of that total is that?

Dr. KATZIN. It's approximately half, since we had side effects in less than half of the population.

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[1] See page 267.

Chairman ROTH. Isn't that roughly 7 percent of the total number sampled?

Dr. KATZIN. Yes, total number sampled in this particular survey.

Chairman ROTH. What percent had side effects of 2 to 3 weeks?

Dr. KATZIN. Of the total population, again, roughly 40 percent of that or about 3.5 percent.

Chairman ROTH. Finally there were——

Dr. KATZIN [interposing]. The last one, as you can see, is——

Chairman ROTH [interposing]. Three weeks or more.

Dr. KATZIN. That is a large category. We grouped them all together at the end.

Chairman ROTH. Let me ask you on that, do you have any idea how long that period was? What was the longest period?

Dr. KATZIN. We don't have the longest on that. We put three or more as a general category.

Chairman ROTH. Did you seek that information or do you just have that——

Dr. KATZIN [interposing]. We didn't wait to get that. This is basically the start of a study to examine the entire Herbalife data base, a tremendous data base from which we can get information about weight-loss problems.

Chairman ROTH. Let me ask you this question. What percent of the total number under this study had side effects? What percent?

Dr. KATZIN. The total number was approximately 40 percent in this particular study of their reported side effects.

Chairman ROTH. Mr. Hughes, you would agree that is considerably higher than the 10 to 15 percent that you estimated was adversely affected, is that correct?

Mr. HUGHES. Yes.

Chairman ROTH. Do you feel——

Mr. HUGHES [interposing]. I might add——

Chairman ROTH [interposing]. Has any study been made to determine whether these side effects resulted in serious impacts on the individual?

Dr. KATZIN. In this particular study there was. There were no serious results in this particular survey.

Chairman ROTH. Did you specifically make that study?

Dr. KATZIN. That was clear.

Chairman ROTH. I would like to see the transient side effects by category, if we might. Doctor, would you explain each of the bars, what they mean and what percentage have the so-called transient side effects?

Dr. KATZIN. If you take a look at the bottom scale, you will see each of the side effects listed according to category—headaches, constipation, diarrhea, nausea, lightheadedness, heart palpitations—and then a general category called "other."

On the left-hand scale is listed the percentage of people who reported side effects. It is not of the total population. This is who reported the side effects.

[At this point in the hearing, Senator Gore withdrew from the hearing room.]

Chairman ROTH. You say these are transient. One of your categories is heart palpitations. Would you not consider heart palpitations a serious matter?

Dr. **Katzin**. Again, this is a subjective report from individuals.

Chairman **Roth**. Nevertheless, the individual thought they had a——

Dr. **Katzin** [interposing]. A heart palpitation.

Chairman **Roth**. Is that serious? What would you advise an individual who thought they had a heart palpitation do?

Dr. **Katzin**. I would certainly advise that individual if it persisted for more than a day or so and had not had it before and they were not familiar with this thing to see a doctor.

Chairman **Roth**. In other words, in ordinary circumstances, if you think you have a heart palpitation, you should see a doctor or did you say——

Dr. **Katzin** [interposing]. Once again, so there is an understanding of what is going on here with individuals, an individual who has been in excellent health and never had a heart palpitation and suddenly drinks a couple cups of coffee and misses a few beats, I don't know that that person needs to go running to his doctor right away. He needs to think about what he did.

An individual who is an older person and suddenly develops a change in his health status, it's a whole different category——

Chairman **Roth** [interposing]. Let me again ask you, Doctor, isn't a heart palpitation a serious matter?

Dr. **Katzin**. It depends exactly what that turns out to be diagnostically.

Chairman **Roth**. Should an individual try to decide for himself or herself whether it is serious or should they consult with a doctor?

Dr. **Katzin**. I would think if an individual is concerned about a side effect he has, he should go to his doctor.

Chairman **Roth**. Isn't the same true about these others——

Dr. **Katzin** [interposing]. The same is true, I would say, about any side effect. If the individual is extremely concerned or if it is severe, he should go immediately to his doctor. I think that is made quite clear.

Chairman **Roth**. We have a rather large group called other. Would you break that down, please?

Dr. **Katzin**. We didn't break it down. This is something for individuals to check so it could be tabulated quickly by a computer. A few people hand wrote in some of what they experienced. Many of those experienced rashes.

Chairman **Roth**. Were any of them of a serious nature?

Dr. **Katzin**. None in this report.

Chairman **Roth**. And you reviewed each one of those?

Dr. **Katzin**. Yes, it was a survey form that was filled out.

Chairman **Roth**. I would appreciate your submitting the underlying data of this study.

Dr. **Katzin**. We can submit a copy of that.

Chairman **Roth**. We will accept that as exhibit 18.

[Exhibit 18 may be found in the files of the subcommittee.]

Chairman **Roth**. Let me go back again. As I understand it, roughly—what is it—41 percent?

Dr. **Katzin**. Approximately 40 percent.

Chairman **Roth**. Forty percent of those that were in this sample did have side effects?

Dr. KATZIN. It is interesting, again, a side effect is a term that is used——

Chairman ROTH [interposing]. What would you describe it as?

Dr. KATZIN. Let me just say something, if I may. A side effect is a word that is used when one gives a medication and it has an effect other than what it was prescribed for. That is called a side effect. When one makes a dietary change, one often experiences certain physical symptoms of the dietary change, as was pointed out. This can occur if you just move to a different State; flying in a plane people often experience constipation; if you go to Mexico, you may experience it from a difference in water, so forth.

It is unclear exactly what to call that except physical symptoms associated with a diet change. It is not clear what aspects of it is due to a diet change. For example, many people begin using milk in their shakes and many people do have gastrointestinal reactions to milk, and people who haven't used milk before making the shakes will react to the milk.

Many people go on a high-fiber diet, start including salads in their program for the first time, and the roughage may cause problems. It is not exactly clear what it is causing these physical symptoms. A number of people, for example, stop eating sugar and stop drinking coffee when they go on this program, and it is well documented that this causes a number of physical effects. It is difficult to come up with the right term and perhaps the best things might have been transient physical symptoms associated with the diet change.

Chairman ROTH. To me—I have to be candid with you--it is a serious matter when you are selling a product, and whatever you want to call it, part of a program when roughly 40 percent have some negative or adverse transient side effects—headaches, constipation, diarrhea, nausea, lightheadedness, heart palpitations. They all can be of some seriousness, although——

Dr. KATZIN [interposing]. But I think that is the question. The question is are they serious——

Chairman ROTH. Isn't the public entitled, I would like to ask you, Mr. Hughes, isn't the public entitled to know when they undertake this program what may be the effects of that program, what may be the transitional side effects?

Mr. HUGHES. Absolutely. And I told the committee here earlier that it has been said verbally to people. You have said——

Chairman ROTH [interposing]. Let me ask you—go ahead.

Mr. HUGHES. As I stated earlier, that it is being said. If it is the suggestion of this committee and several other committees, I already said this company is open and willing to look at things. If that is a very serious suggestion, this company will take a look at it and make some—we will contemplate possibly making that change.

Chairman ROTH. Let me ask you this basic question. Don't you as an entrepreneur feel that it is important that the individuals who buy your program, including its products, should be on notice as to what may be the possible effects?

Mr. HUGHES. They are. It's something that has been talked about in our company since before the company even began. It is not something that is hidden.

Chairman **Roth**. If I understand——

Mr. **Hughes** [interposing]. I want to get my statement on. It is nothing that has been hidden. It is something talked about in every training class. If you want to get a tape on our training class, you are more than welcome to look at it. If it is on tape, cassette, it is nothing that is hidden.

Chairman **Roth**. Again, though, it is word of mouth. Why don't you put the same kind of warning, for example, on as the Cambridge Diet? Would that be appropriate to put on your product?

Mr. **Hughes**. I do not feel that it would be the same appropriate situation for us to put the same label that Cambridge has on its product because I haven't seen the particular label that they showed you. I think it may have been on their original product. That label stated that the consumer should use the product three times a day and eat no food. That clearly is something entirely different than what we are doing here.

Chairman **Roth**. Wouldn't it be appropriate to give some kind of warning based on the experience of your product and your program?

Mr. **Hughes**. Let me say this: I do not think there is any harm from someone getting good, sound, basic nutrition. We have not had any complaints. If it is the suggestion of this committee to put that on the product, we will take that under consideration.

Chairman **Roth**. What I am asking you is, based upon this test done by your own adviser, don't you feel it is important that such warning be given in writing and not relied upon through word of mouth?

Mr. **Hughes**. I'm not opposed to it, but I am not willing to say yes at this particular time. We will certainly take it under consideration.

Chairman **Roth**. While we are waiting for Mr. Gore to come in, what are the purposes of the herbs contained in the product?

Mr. **Hughes**. Basically to help with the appetite and to help cleanse.

Chairman **Roth**. When you say "help with the appetite," what do you mean by "help"?

Mr. **Hughes**. Help with the appetite; I don't know how else to say it.

Chairman **Roth**. Is that the same as suppress?

Mr. **Hughes**. Help.

Chairman **Roth**. Let me ask you this. Which herbs suppress the appetite?

Mr. **Hughes**. I don't have the documentation right in front of me, but there are nine of them in there.

Chairman **Roth**. You don't know which ones have that effect?

Mr. **Hughes**. I have to have the documentation in front of me. I don't have the sketchings and the products in front of me.

Chairman **Roth**. Is it also alleged or claimed that the herbs——

Mr. **Hughes** [interposing]. But you have it in front of you.

Chairman **Roth** [continuing]. Cleanse the system; is that part of the claim?

Mr. **Hughes**. Yes; it is.

Chairman **Roth**. Could you tell me which herbs cleanse the system?

Mr. HUGHES. Just about all of them.

Chairman ROTH. Have you made clinical tests or examinations, scientific clinical tests to determine whether, in fact, these herbs in the proportion of the kind you use do, one, cleanse the system? Have you had any such tests done?

Mr. HUGHES. We have a lot of scientific data on the herbs. If that is what is necessary, we are prepared to submit that to the committee.

Chairman ROTH. That is not my question.

Mr. HUGHES. I think what you are trying to say is are we able to substantiate things about each one of the ingredients. We are more than prepared to submit that to the committee. If you are asking did Herbalife do a scientific study of those particular ingredients all combined together, the answer to that is we are not prepared to submit that today. It was the suggestion of the committee that we do that and this hearing was supposed to be—we were asked and we wrote to ask to postpone this for 90 days and this committee refused to allow us to do that. That study is taking place at this moment at the University of San Diego.

Chairman ROTH. Let me again ask you, you say you are undergoing certain tests, but by inference——

Mr. HUGHES [interposing]. Everything together.

Chairman ROTH. By inference, if I understand you, you have not made scientific tests or clinical testing of your products with the various herbs they contain to determine what are the cleansing effects, is that correct, at this stage?

Mr. HUGHES. This has been done on each one of the ingredients, and we can document that. If you want to know if Herbalife had done a specific test——

Chairman ROTH [interposing]. Yes; I am asking whether you made specific tests.

Mr. HUGHES. Those tests are ongoing now. Also, this is a food——

Chairman ROTH [interposing]. When did you begin those tests?

Mr. HUGHES. I believe approximately 1 month ago. It is not something that you have to do by regulation, by Food and Drug Administration, so we have never done it.

Chairman ROTH. As a provider of such products in a program, don't you have a responsibility to ensure that the products you sell do what you claim they do and are safe for those that use them?

[At this point in the hearing, Senator Gore reentered the hearing room.]

Mr. HUGHES. I think that was made perfectly clear today. FDA said the ingredients were safe and, indeed, they are. We have millions of people using them that works for them. I don't know why it is being totally ignored. Everybody is flaming it up to where it is just bad. There are millions of people using it. It is safe and effective, and it is not hurting people. I don't understand why that is not being heard. Why is it the 10 billion portions of the product that has been used is not any kind of scientific testing. I don't think they have given 9 billion portions to some small rats.

Chairman ROTH. Let me point out, I go back again to your earlier testimony, you said there were side effects roughly of 10 to 15 percent.

Mr. **Hughes**. Because my—excuse me.

Chairman **Roth**. One test or examination that has been submitted would show that it is as high as 40 percent. So that it does seem to me this is a serious matter that you ought to deal with and, I think, have a responsibility to assure there is adequate testing. We have Senator Gore here.

Mr. **Hughes**. Is that your recommendation? We can take that up?

Chairman **Roth**. Let me say, the purpose of the committee is not to try to make recommendations to you. That is a matter for the agency to have that responsibility. Let me defer to Senator Gore.

Senator **Gore**. Thank you very much, Mr. Chairman. You said just a moment ago, Mr. Hughes, that FDA testified that the herbs were safe. I don't think they precisely said that. You correct me if my memory is wrong, but what I heard them say is that some of the herbs were harmful, but the low doses found in Herbalife products did not warrant the allocation of FDA manpower in order to pull the products out of distribution. I believe that is what I heard.

Mr. **Hughes**. I think I heard they were talking about two specific ingredients—mandrake and poke root—which we removed from the products 6 weeks after they sent us a regulatory letter and we voluntarily took it out of the product.

Senator **Gore**. I believe his statement on the manpower allocation was, in fact, directed to the mandrake and poke root. I don't think I heard them say they were——

Mr. **Hughes** [interposing]. I think someone on the committee asked about comfrey and chaparral.

Senator **Gore**. Again, two specific products. I think that it is—I had never heard of Herbalife until last week when Chairman Roth notified members of the subcommittee that this hearing was coming up. I may be one of the few who hasn't heard of it. I don't know, but I had not. Since I found this hearing this morning was to take place, I have tried to study the literature and look at the allegations that have been made and in some ways it is a trick set of issues, and I have been trying to puzzle through exactly why that is the case.

Some programs, like yours, have what the witnesses yesterday described as a placebo effect and, in addition, the witnesses didn't accept this distinction necessarily yesterday, but in my view it is a distinction, they also make it easier for people who want to lose weight to pay attention to what they are eating, how much they are eating and, as a result, it is my belief that many people will lose weight with almost any kind of a diet if they stick to it and if they reduce their caloric intake.

It is my personal belief that the numbers of people who have said, yes, they lost weight as a result of your program; yes, they believe it works, had that experience of those two effects.

Now, the questions remaining are, number one, the nature of the marketing scheme which I don't think we have really gotten into, but the State of California is interested in that, whether it is a chain or a pyramid which is deemed to be harmful because eventually all such enterprises collapse. Your folks say no, it is not because they are on three levels, et cetera, but that is a legal question that I think the State of California is pursuing.

The other issues are, will this program or diet be harmful to some of the people who go on it and is it surrounded by claims that are inaccurate and/or irresponsible?

Now, there are reports of people suffering harm as a result of the diet. They fall in the category of people who are told by their doctors not to consume caffeine, for example—that is one set of reports—and your people will sell them items that have caffeine and you don't tell them that it has caffeine. There are other examples.

On the question of claims, are they responsible and/or accurate? Again, that is a trick set of issues because of the distinction between your statements and the paid testimonials of people who are describing simply what is happening to them.

Mr. HUGHES. Paid statements?

Senator GORE. I think Senator Rudman—let me clarify that because you are right. Paid statements in the sense that you pay for the television time to broadcast their testimonials, not paid in the sense that they are reimbursed for giving their opinion, although many of those who make such testimonials have a personal economic stake in promoting a favorable impression of the product because their livelihood depends upon it.

Now, I know that not everyone who takes the product is a distributor. Not everyone who says I think it's a good product is a distributor. But in your magazine, Herbalife Journal, in fine print here on the inside cover, it says:

"Herbalife welcomes your contributions of articles and news," blah, blah, blah, "remember, too, we will pay $200 for signed weight loss and product testimonies if we publish them in the journal."

Mr. HUGHES. Just in the journal, not in the television shows you are talking about.

Senator GORE. Well, but someone who reads this journal and reads the personal testimony of someone who says I had arthritis and right after I took Herbalife products, my arthritis went away, then that—if you pay that person $200 for the testimonial that says my arthritis went away after I took Herbalife products, then you are in a sense claiming that Herbalife products cured that person's arthritis, wouldn't you agree?

Mr. HUGHES. No, we do not. We do not say that the product cured it. The $200 is given to someone who has lost weight and whose testimonials is printed in the Herbalife Journal period. That is where they have submitted pictures to us and supplied written testimonial, and for them to go buy a set of clothes. Indeed, we have thousands and thousands of testimonials we never do use; they go into our files. That is only one form of publication.

The largest of the testimonials given in the company are in the distributor rallies and the majority of all those people, because when we do our rallies, for example, this month we do approximately 15 of those, myself and the vice president, there will be thousands of people we hear from and those people are not in the journals and they are not paid.

Senator GORE. What is the significance if it is in the journal or not in the journal? The journal is given to prospective customers, isn't it?

Mr. HUGHES. It can be shown to prospective customers.

Senator GORE. And is, isn't it?

Mr. HUGHES. Sure.

Senator GORE. If you pay for a series of testimonials——

Mr. HUGHES [interposing]. I don't get the point. There is no hidden fact we paid——

Senator GORE [interposing]. Pardon?

Mr. HUGHES. It has never been a secret that we paid for people's stories to be used in the journals.

Senator GORE. I am not charging you with making a false statement. A moment ago you questioned my use of the paid testimonials. That is the reason I highlighted it. I accept the fact you may have just forgotten the testimonials are in the magazines are paid for.

Mr. HUGHES. I said not on the television shows.

Senator GORE. All right. The question is if a prospective customer is given the journal and you pay for a series of testimonials that has a clear message that a particular disease has disappeared after use of Herbalife products, then how can you disassociate yourself from that claim, from that message?

Mr. HUGHES. I understand what you are saying and, indeed, this is a big problem with us, and I have said here several times to the committee, that if anybody has suggestions, we would appreciate hearing from them. When someone goes on—let's take the weight control product for just a minute. If they lose, let's say, 50 pounds, the AMA have said it—the U.S. Department of Agriculture has said it—it is very likely that person will not have as much pressure on their heart; they may be taking less blood pressure medication.

We have a tremendous number of customers getting on the product, as a result of losing weight, they are gaining—they say, "I am not taking as much blood pressure medication, my heart doesn't beat like it used to; I don't have to take my nitroglycerin tablets." When we print the journal, and when we put the testimonials on the television shows, we specifically take those testimonials and we edit those testimonials.

If you were to see the written documentation on what we get compared to what you see in the magazine, you would see that they are entirely different things—unless we specifically have them rewrite the letters. When you see the testimonials given randomly in front of people and everybody gets up and says "I got on the product and I lost 100 pounds on the product and as the result of losing weight, my blood pressure has gone down," we know as a company we can't say, "Hey, listen, we cured their blood pressure," we clearly know that, and this is a problem area for us. That is why I said before that there have been only two live broadcasts. After those two broadcasts, we had two attorneys look at them and edit the testimonials. We did have a problem——

Senator GORE [interposing]. I am prepared to believe that many disorders can, in fact, be associated with obesity and when weight loss occurs due to reduction in the ratio of calories and energy burned that some problems will go away.

I think—maybe I am misled—but I think that sometimes does occur. But it seems to me when you say it is a big problem for you—that is kind of an understatement because it is a big problem for people who are approached by your distributors if they have a disease and the distributor gives that person a testimonial, either written or personal, that implies that disease can be cured by your products, then that is a big problem for that person; don't you agree?

Mr. HUGHES. If someone said what you just said, when they go to someone and said this product, because it happened to them, would cure your high blood pressure or would cure anything, this company would terminate that person. That is very, very clear.

Senator GORE. But it seems to me the way the system operates seems to encourage that because of just the way it is structured. You rely on testimonials; you rely principally on these testimonials, and the individuals are undersupervised; they get out there; they know the testimonials work——

Mr. HUGHES [interposing]. That is not true that they are not supervised.

Senator GORE. Pardon me?

Mr. HUGHES. It is not true they are not supervised.

Senator GORE. Maybe I am using the word "supervised" in too loose a way. Because they are independent, they are independent contractors, right, so they go out and operate on their own, but you give them a set of guidelines; is that what you mean by supervision?

Mr. HUGHES. No; there is also an inherent supervision from all the distributors. If one distributor does it and the other distributor who lives down the street cannot do it, they have a tendency to get very, very mad and, as a result, they end up calling our distributor relations department which is approximately 71 people that handle these people and we deal with them.

Senator GORE. I think it is an open question, at least in my mind, how effective a mechanism like that would be. I accept it for what you say it is. There was an example brought to the attention of this subcommittee in Nashville, TN. We received a statement from a Bernard Lehman who said an Herbalife distributor sold him products that he said would cure his cancer. Are you familiar with this case?

Mr. HUGHES. No, I'm not.

Senator GORE. Anybody on the panel familiar with this case?

[No response.]

Senator GORE. What is your reaction to a situation like that?

Mr. HUGHES. It's a complete violation of our marketing plan. It says right in our career book which you have, no distributor shall make such medical claims. It is clearly defined in our rules and regulations, and the person is subject to termination.

What we would do as a company, just so you will know, and I tried to say this a little bit earlier, we as a company, if we found out the person's name, we would write to the individual and say we have found out you committed the following offense. We would stop all their buying privileges; we would stop any bonuses for them to be received by the company. They would have to write back to the company within 15 days and say I have committed these situations in violation of Herbalife's marketing plan, and if they commit it a second time, they will be terminated from the company.

Senator GORE. It seems to me given the kind of reports that led to this hearing, given——

Mr. HUGHES [interposing]. Can we discuss that for a second? Can I make one comment?

Senator GORE. Sure.

Mr. HUGHES. Because it is relative to what you are saying. On the CNN broadcast which I think probably led to a lot—Mr. Rinzel reported to me that is primarily how it got started.

Mr. RINZEL. That is absolutely incorrect, Mr. Hughes.

Mr. HUGHES. I heard about the CNN—was it from Mr. Shapiro?

Senator GORE. There were a number of reports in Forbes magazine, a number of other publications, and I think some individuals contacted the subcommittee. What I started to say, and then I will give you a chance to comment, given the kinds of reports which we have received and which led to these hearings, it seems to me you have a responsibility to have a proactive response rather than just a reactive response. If you have repeated instances of apparent claims being made to customers that there is a connection between your products and the curing of various illnesses, it seems to me you have a responsibility to proactively go out and try to stop them, and the implication is left if you simply react and wait for the telephone to ring from one distributor tattling on another, the implication is left that the tremendous revenues that are coming in you feel might be threatened by a more aggressive effort to stop these kinds of marketing practices.

Mr. HUGHES. I don't feel that is—we don't feel a threat that that is going to happen. If it was something at the suggestion of this committee maybe Herbalife was to say—I don't know how we would accomplish that is what I am trying to say. If we were to put in our literature do not talk about high blood pressure, do not talk about this, this and this, we would certainly be willing to put it in our literature. I just don't know if that will accomplish it, per se.

We are open for suggestion, and we are certainly willing to think about it.

Senator GORE. Mr. Chairman, I had some other questions, but many have been covered. I got your note on time running out.

Chairman ROTH. Senator Rudman.

Senator RUDMAN. I really don't have any more. I want to follow up on Senator Gore's excellent line of questioning. What Senator Gore is trying to establish is the atmosphere, what is the environment which is taking place. I would like to talk with you about that, Mr. Hughes, for a moment.

Last night, you had a rally here in Washington, very well attended, at the Washington Armory.

Mr. HUGHES. Yes, we did.

Senator RUDMAN. About how many people were there?

Mr. HUGHES. Roughly 3,000, 4,000.

Senator RUDMAN. And there were members of our staff there also because it was open to the public. And at that meeting, it was a good sales meeting in terms of your business purpose to sell more of your product. Nobody really has a problem with that. But at the end of the meeting, or toward the end of the meeting, at some point a gentleman named Larry Thompson, who was the emcee of the meeting—and what is his position?

Mr. HUGHES. Executive director of sales.

Senator RUDMAN. Mr. Thompson got up and he solicited for anyone who wanted to come up to tell the audience of 3,000, whatever, what Herbalife has done for them. That's accurate; isn't it?

Mr. HUGHES. Yes, sir.

Senator RUDMAN. And a number of people came up and talked about Herbalife had done a great deal for them in terms of weight reduction.

Mr. HUGHES. Yes; that's true.

Senator RUDMAN. In addition, there were three other people that got up. From my understanding of how you satellite this around the country, not this one I am talking about, but your general marketing plan, this is a very interesting occurrence because it happens everywhere your distributors run these programs.

Mr. HUGHES. It is blocked out on the satellites.

Senator RUDMAN. I didn't say it was on the satellite.

Mr. HUGHES. I want you to know it is specifically blocked out. If anybody gets it on the satellite, they do not see what is going on in the room during the testimonial time.

Senator RUDMAN. Right, but, of course, they sometimes have those testimonials given during that break at that place in New Hampshire or Tennessee, wherever that is going on. They have their live testimonial there. They do not have to get it off the screen; right?

Mr. HUGHES. They give their testimonials about what is happening——

Senator RUDMAN [interposing]. What happened last night, because Senator Gore made a very interesting point as to proactive and reactive and why some of us are not convinced by your testimony here, Mr. Hughes, there were three people who gave testimonials last night. Granted, it was only 3,000 people and granted, you didn't broadcast it. One said, paraphrasing, that they had diabetes and they took Herbalife and their diabetes was cured. They didn't say Herbalife cured the diabetes, but they made the statement, they had diabetes, was suffering from it, they took this product, they no longer have it.

The second person said they were told by a doctor that they had a dying child; that they put the child on some of the products and the child didn't die. Again, they didn't really make the connection. They didn't say and it was because of Herbalife, but they did, of course, say that they had taken Herbalife and the child didn't die, and I kind of assume with basic logic there must be some connection the human mind makes between the two.

The third person was a person who said they were on crutches for some time; took Herbalife products and no longer on crutches. Didn't say Herbalife really was the cure. Mr. Hughes, do you think you are running a first-rate, top-notch weight reduction company that maybe not ought to allow that kind of thing to go on in your halls that you are paying for?

Mr. HUGHES. First of all, there were many more than just three people that gave testimonials last night, and at the end of the conversation, you also heard Mr. Thompson say Herbalife does not cure anything; what it does is give people good, sound, basic nutrition.

Senator RUDMAN. I know there is a disclaimer, Mr. Hughes. Mr. Hughes, let me simply tell you, as your lawyers will tell you, disclaimers work to a point. You didn't answer my question. Very simple question. Do you think—you talk about this committee not making suggestions to you, that is not our purpose, but do you think possibly you maybe ought to clean up your act in the sense that you discourage people from getting up there and talking about all these wonderful cures? I wonder if you could answer that for me in your own words and maybe not the words of your counsel.

Mr. HUGHES. Yes; I do think we should, and we are trying to do that. We have people working the lines now. I agree with you.

Senator RUDMAN. Doctor, I only have one question for you. I found your charts very interesting. I found the conflict between your testimony and Mr. Hughes' testimony a little surprising because your charts indicate, and they may be minor side effects, but you drew the chart, I didn't; you call them side effects. Roughly 40 percent of the sample had some variety——

Dr. KATZIN [interposing]. Of something, yes.

Senator RUDMAN. Mr. Hughes said 15 percent. You have briefed Mr. Hughes on the results of this work you have been doing?

Dr. KATZIN. In point of fact, I have. Unfortunately——

Senator RUDMAN [interposing]. Have or haven't?

Dr. KATZIN. I have and these particular charts, however, were not finished until midnight last night where all the data was very clear. I did not have a chance to give him a full briefing this morning.

Mr. HUGHES. My 10 to 15 percent comes from talking in rooms with thousands of people. When I talk about the subject to the distributors, they raise their hands and let us know what the problems are. It has been from over the last 5 years, and we have seen literally hundreds of thousands of people raise their hands. That is where I got the 10, 15.

Senator RUDMAN. In fact, you brought a lawsuit against the Food and Drug Administration for alleging a 25-percent side effect figure.

Mr. HUGHES. We brought the suit against the FDA for one reason. In 1982, we were sent a notice of adverse finding. We corrected the situations within 6 weeks and for approximately 3 years, that letter was distributed in all 52 agency offices, and we asked specifically for many years for them to at least be a responsible agency and to correct their files.

We feel for the last 2 years we have been specifically harassed in the newspapers because the FDA specifically out of their local offices sent those old situations to the media and, as a result of that, I feel the California attorney general thought that there was a 2-year period in which this company was not complying with the FDA, but during which, in fact, there were numerous conversations.

When the attorney general called this company, we were very, very cooperative. We now have had our four meetings with them and making very good progress. I felt it was irresponsible on their part. We sued them specifically to do one thing—to update the files. The minute that was done, we dropped the suit.

Senator RUDMAN. They did, in fact allege a 25-percent rate and you specifically complained about that in your lawsuit? That is a simple question; simple yes or not about it.

Mr. HUGHES. Yes.

Senator RUDMAN. Doctor, one really last question for you. I looked at your curriculum vitae and see you have done research in various places. You have a degree in chemistry; you have a Ph.D. and you have an M.D. Would you say that a test, a clinical evaluation of 300 or 400 people that lasted over a 3-month period that did not in any finite way specify the kind of side effects, how long they were, whether they had followed up—is that the kind of clinical test that you would present to a medical society or to your alma mater, or was this just kind of done kind of quickly? It didn't turn out too good for you, maybe the numbers are lower than 40 percent; do you want us to believe that is your representation of a true clinical study, a few hundred people for 3 months?

Dr. KATZIN. Well, the study occurred over a 3-month period, but it covered a retrospective period up to 5 years. If you look at this week's Journal of Medicine, American Medical Association, you see two studies that are retrospective studies. It is absolutely an accepted form of gathering data from a population.

Senator RUDMAN. That is correct, but you did not truly personally gather the retrospective data?

Dr. KATZIN. Of course, I did.

Senator RUDMAN. I am saying you had no way of following that data going back 5 years.

Dr. KATZIN. I guess there is a confusion in your mind as to exactly what retrospective means.

Senator RUDMAN. I think I understand the meaning of the word, Doctor.

Dr. KATZIN. Do you?

Senator RUDMAN. Oh——

Dr. KATZIN [interposing]. Why don't you explain it to me so we have the same concept? Retrospective study is one in which you review data from previous years.

Senator RUDMAN. That is correct.

Dr. KATZIN. A prospective is one which you follow data that has not yet appeared in the population.

Senator RUDMAN. But the fact is most clinical studies that are retrospective and have published the information that was studied was generally under some kind of control by the clinicians who developed the study; is that not true?

Dr. KATZIN. That is exactly not true of a retrospective study because it just gathers data from a population base that is already there. There can't be a control. That is a prospective study.

Senator RUDMAN. Your population base is a very special population base.

Dr. KATZIN. Which is?

Senator RUDMAN. It is a population base of people who use this product.

Dr. KATZIN. Exactly. That is what we were studying; we were studying the people who used the Herbalife product not the people who walked down the street on Saturday afternoon. We can do it to them——

Senator RUDMAN [interposing]. Your clinical study does not in any way indicate the kind of activity that you have in your chart to the general population over the same period of time.

Dr. KATZIN. No, it doesn't compare it to that.

Senator RUDMAN. I know there are people in this city who don't use your products who have all the same kinds of symptoms—diarrhea——

Dr. KATZIN [interposing]. Precisely.

Senator RUDMAN. What I am saying to you is in terms of a quote, if you want to use retrospective study over a 3-month period, it is probably not the kind of thing you would want to publish or probably wouldn't be published in a learned journal. It just isn't deep enough; the sample isn't big enough; the comparison and test control aren't big enough. If you presented this as a clinical study based on your curriculum vitae, I say to you, Doctor, you may be very good in what you do, but that is not a clinical study.

Dr. KATZIN. If you remember an exact statement about the study, it is an ongoing study, ongoing of the population which, if we had the time, I would be happy to have done. I think the preliminary results are quite interesting in that we did study a population that had been on the program for more than 1 year and this is the data. The control population would be the norm as published in journals in which fewer than 10 percent maintained their weight for more than 1 year.

Senator RUDMAN. Let me ask you, Doctor, are you under a long-term contract with this company?

Dr. KATZIN. Not at this time.

Senator RUDMAN. What were the general terms of your employment? How long were you told you would be employed for when you were hired?

Dr. KATZIN. That really is in the process of negotiation right now. Things are moving quickly, as you can imagine.

Senator RUDMAN. Who hired you, Mr. Hughes or Dr. Marconi?

Dr. KATZIN. Mr. Hughes.

Senator RUDMAN. Do you know Dr. Marconi?

Dr. KATZIN. Yes, I do. I prefer to call him Mr. Marconi or Dick Marconi.

Senator RUDMAN. Does he have a bona fide doctorate degree, to your knowledge?

Dr. KATZIN. I don't know what he's got. [Laughter.]

Senator RUDMAN. You don't know. Do you know that college I mentioned out in California with the strange name?

Dr. KATZIN. Donsbach University. I know it only by name.

Senator RUDMAN. Do you know anything about it yourself?

Dr. KATZIN. I know next to nothing about it only when it first came into being it was supposed to become a major correspondence university of which many of these things have a good reputation. It was initially approved by the California Nurses Association as a valid way of gaining credits, and so forth and so on, and something has happened in the past couple years.

Senator RUDMAN. Are you aware Mr. Marconi claims his doctorate is from that institute?

Dr. KATZIN. I am aware of that.

Senator RUDMAN. Thank you.

Chairman **Roth**. Senator Gore.

Senator **Gore**. Mr. Chairman, I will not take up much time. In all fairness, I believe I have consumed less time. I am only on my second round. I believe Mr. Rudman finished his third, if I am not mistaken. I won't take very long.

I wanted to ask just two more lines of questioning. I wanted to come back to the caffeine issue. You have a product called NRG and some people are sensitive to caffeine. Some people have health problems where their doctors advise them not to take caffeine. You are aware of that. Your vice president, Thompson—what is his first name?

Mr. **Hughes**. Larry Thompson.

Senator **Gore**. The executive vice president, the fellow you were talking about earlier. He wrote a letter on June 8, 1984, to Dr. Howard Posner in Philadelphia who became aware, and I am reading here from the Los Angeles Times article——

Mr. **Hughes** [interposing]. You are saying Larry Thompson wrote something?

Senator **Gore**. Yes;

> Dr. Howard Posner became aware of Herbalife when several of his patients who were taking NRG tablets complained of heart palpitations, sleeplessness, anxiety, symptoms similar to caffeine toxicity.

This according to the LA Times article. Dr. Posner wrote to Herbalife twice to ask about the report that caffeine was in the product that his patients were taking. And his patients were told, according to him, that the caffeine had been "inactivated" in NRG and he submitted for an independent analysis at the same time.

According to this article, your vice president, Larry Thompson, wrote a letter back to Dr. Posner on June 8, 1984, and said,

> Because our products are dietary, nutritional supplements, clinical studies are not required. However, I can confirm that guarana from our product NRG has the same chemical composition as caffeine but works on the adrenal system as opposed to caffeine which works on the central nervous system.

I would like to ask you, Dr. Katzin, whether you agree as a doctor with the opinion expressed by the executive vice president for sales?

Dr. **Katzin**. I don't know if that quotes him directly or if he was using terms I would use. I would agree with some of it, and I would disagree with some of it.

Senator **Gore**. Let me ask you about the key part. Do you agree it works on the adrenal system as opposed to caffeine which works on the central nervous system?

Dr. **Katzin**. I don't have information about that. There is a question of the effect of caffeine on the adrenal system. I would say caffeine is caffeine personally. I would say they work the same. I would disagree with that statement.

Senator **Gore**. Fine.

Mr. **Hughes**. Can I say one thing?

Senator **Gore**. Sure.

Mr. **Hughes**. This has been a big issue, this caffeine, over the last couple of months. I am getting a little tired about it, quite frankly. By the FDA rules and regulations, guarana has never needed to be labeled anything other than the way it is labeled presently, just as if chocolate does not show caffeine in it also.

There has been such a large amount of people saying it. There's approximately, about 3 percent of a 800-milligram tablet which does contain caffeine, roughly 24 milligrams of an 800-milligram tablet.

Senator GORE. Wait, give me the figures?

Mr. HUGHES. Roughly 3 percent, or in an 800-milligram tablet, there would be approximately 24 milligrams of caffeine which would be about a third of a Coca-Cola——

Senator GORE [interposing]. No; that is not right. According to FDA, a 12-ounce Coca-Cola has 40 milligrams, and according to the laboratory analysis of NRG, it has 30 milligrams and you recommend four tablets per day——

Mr. HUGHES [interposing]. What I was going to say is this: We have never had a formal complaint against the NRG product. We heard so much about it we are going to list it on the label voluntarily. FDA does not require it; it is not a requirement of the Food and Drug Administration. We are putting it on there voluntarily.

Senator GORE. I think that is good. I think that is what you should do, and I would just say for the record, I think there is a big distinction between a product like chocolate and a product like NRG which is specifically sold with claims that it is an energy stimulant. That is what it is sold for. It gives you a kick.

Mr. HUGHES. Yes.

Senator GORE. And then if it is coupled with the statements by distributors that the caffeine has been inactivated, or statements from your executive vice president that it doesn't work on the nervous system like caffeine——

Mr. HUGHES. I don't know if he wrote that, per se.

Senator GORE. The article could well be wrong, but there it is.

Mr. HUGHES. We appreciate the comments.

Senator GORE. Fine. One other question, and I will do this very briefly, Mr. Chairman. We heard testimony yesterday from Dr. Tyler that a number of herbal ingredients in these products were at levels too low to have any effect. Licorice was one. There were others, I believe. Again, I want to ask you, Dr. Katzin, do you disagree with the reported statement in this article about caffeine? Would you agree with Dr. Tyler's testimony yesterday that the levels of some of these herbs are too low to have any effect whatsoever?

Dr. KATZIN. I don't think I can agree completely with that. I would certainly agree with the following:

They are too low to have a therapeutic or medicinal effect. However, the exact lower effect on the body and whether there is not a synergistic effect of several herbs acting together, I can't say for sure; I think that is open for discussion. Certainly I can say they are below medicinal levels and below toxic levels.

Senator GORE. Very good. Thank you.

Chairman ROTH. Mr. Rinzel has a few questions.

Mr. RINZEL. Thank you, Mr. Chairman. Mr. Hughes, it is my understanding that the medical panel which Herbalife now has in existence, of which Dr. Katzin is the head, was established in April 1985; is that correct?

Mr. HUGHES. Excuse me, I didn't hear that.

Mr. RINZEL. My understanding is that the medical panel, panel of medical experts, nutrition experts of which Dr. Katzin is the head, was established by Herbalife in April 1985; is that correct?

[At this point in the hearing, Senator Gore withdrew from the hearing room.]

Mr. HUGHES. It is inaccurate. It was established right around the first of the year.

Mr. RINZEL. The first of the year?

Mr. HUGHES. That is correct. Indeed, some of the people that are involved with the company either directly or with Dick Marconi's operation out of D&F Industries have been associated with the company for more than 3 years; one of them 5 years.

Mr. RINZEL. Dr. Katzin didn't get on board until several months ago; isn't that correct?

Mr. HUGHES. Dr. Katzin, right around the first of the year; that's correct.

Mr. RINZEL. First of the year?

Mr. HUGHES. Yes.

Mr. RINZEL. Dr. Katzin, when did you start doing active work for Herbalife?

Dr. KATZIN. I began working for the scientific advisory board, which is related with Dick Marconi, in February.

Mr. RINZEL. Isn't it true that in 1983, your public relations firm suggested and recommended that you appoint a medical advisory board, nutritional advisory board at that time and that recommendation was rejected by you?

Mr. HUGHES. With the firm we were with, yes, it was very seriously not under consideration with that firm. That's accurate.

Mr. RINZEL. Why is that?

Mr. HUGHES. Because the people they were bringing forward were not to my qualifications.

Mr. RINZEL. You didn't like the type of people they were recommending?

Mr. HUGHES. No, I did not.

Mr. RINZEL. Why didn't you like them?

Mr. HUGHES. Because they weren't willing to use the products every single day.

Mr. RINZEL. They weren't willing to use the products——

Mr. HUGHES [interposing]. Exactly, and I don't think anybody can properly represent this company and lose weight and not use it very single day. That is my personal belief. I don't think they can represent my company unless they use it and believe what I am doing.

Mr. RINZEL. Does that mean all the people on your advisory board, as a requirement of being on the board, must use the product?

Mr. HUGHES. Well, we don't have that in language, if that is what you are trying to say. I know they are using the products and, indeed, we have had several doctors with the company, and it took us a while to develop the board that we now have. Dr. George Picus has been associated with Herbalife, not employed by Herbalife, for over 3 years. Paul Satadwan, Ph.D., helped develop several of the products for the first Moon launch working with NASA. It has taken a while to develop the kind of people we want. Just like any staff, it takes a while to develop. This is a young company, by the way. We are only 5 years.

Mr. **Rinzel**. I don't have any more questions, but I would like to make a statement for the record in the death cases. Staff did obtain all the autopsy reports that were available regarding the Herbalife death cases. There is none yet available on the Tyson case in Florida. No autopsy has been prepared. We did obtain the Bivian Lee autopsy, and we did obtain the autopsy of the 20-year-old woman who died in Albuquerque. Those autopsy reports were made available to Dr. van Itallie who submitted an affidavit which is part of the record.

The fifth death which the FDA mentioned today the staff is not aware of. I assume that is a very recent matter, and we will obtain information about that to add to the record.

[Mr. Hughes' prepared statement, supplemental statement, and responses to written questions submitted by Senator Glenn follow. Dr. Katzin's prepared statement with attachments also follows:]

STATEMENT

OF

MARK HUGHES
PRESIDENT AND FOUNDER
HERBALIFE INTERNATIONAL

BEFORE

THE

SENATE PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS

CONCERNING

WEIGHT REDUCTION PRODUCTS

ON

MAY 15, 1985

Chairman Roth and Members of the Permanent Subcommittee on Investigations:

As the founder and president of Herbalife International, allow me to begin my remarks by stating how pleased and professionally gratified I am to be appearing before you.

Herbalife, as one of the largest nutritional supplement companies in the world, welcomes the opportunity to be a part of this Subcommittee's effort to inform the American consumer about the worthless products which are threatening the reputations of the responsible companies who are committed to the health and well being of the people of this country.

My philosophy in founding Herbalife was to base a weight reduction program on the fundamentals of good, sound and basic nutrition. Clear distinctions between Herbalife and other products must be made. Experts agree that effective weight loss can only occur when the number of calories expended exceeds the number of calories consumed. Our program, which provides a balance of proteins, carbohydrates, fats, vitamins and minerals succeeds because it combines the basic nutrition offered by high quality food supplements with one well balanced meal a day selected by the consumer in accordance with recommendations made by the company.

Nothing more eloquently argues for the need for safe and effective products to help people with their weight problems than the excesses to which people are willing to go in misguided efforts to lose weight. The public has been innundated with obviously worthless products such as reduction wraps, reducing creams and fanciful notions of fruit-based compounds to dangerous procedures involving hormones, amphetamines and extensive surgical alteration of the body. By contrast, Herbalife has pledged itself to providing the highest quality products available.

I pride myself on the company's history of cooperation with the Food and Drug Administration. We have always been willing to accommodate the legitimate concerns of the staff of the FDA and we remain willing to do so.

This Subcommittee has undertaken an enormously complex and difficult task in attempting to review the nutritional supplement and weight control industry in less than two days of public hearings. Speaking on behalf of our millions of satisfied customers, I wish to express my regret that you were unable to find the time to hear from the eminent medical and nutritional experts who support and approve of our products and to hope that the American people will take the time to fully inform themselves on the clear superiority of the Herbalife program over the alternatives which we all soundly condemn.

Thank you.

SUPPLEMENTAL STATEMENT OF
HERBALIFE INTERNATIONAL TO
THE SENATE PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS CONCERNING
WEIGHT REDUCTION PRODUCTS AND PLANS

May 14-15, 1985

Introduction

During the course of the hearings on Weight Reduction Products and Plans before this Subcommittee on May 14 and 15, 1985, the products and activities of Herbalife International were the focus of a disproportionate amount of testimony and inquiry. While Herbalife does not shrink from this examination, and, indeed, welcomes colloquy with the appropriate regulatory agencies, the Subcommittee's failure to examine so harshly and in so searching a manner the dozens, if not hundreds, of less responsible and less effective weight reduction programs, and its concomitant failure to give equal attention and time to Herbalife's proponents as it gave to its critics, leads Herbalife to believe that the record, as it now stands, is incomplete and inaccurate with respect to both Herbalife and its products. Therefore, in accordance with the Chairman's invitation to provide additional statements or responses to questions, Herbalife respectfully submits this supplemental statement in an effort to present its position fully, fairly and clearly and to dispel unwarranted criticism of and unfounded fears about its products.

As Mr. Hughes told the Subcommittee, Herbalife International is only five years old. During that relatively short period of time Herbalife has experienced extraordinary success and equally extraordinary growth, simply because its nutritional program works, and works better than any other program in the marketplace. Many organizations that have experienced enormous growth in so short a period have also experienced growing pains when they discover that what works well for a small company does not work necessarily as well for a larger organization. To some extent, Herbalife has experienced such growing pains. Nevertheless, Herbalife recognizes its responsibility to the public and will, whenever necessary, take appropriate ameliorative steps. This is consistent with Herbalife's past actions. For example, in 1982 when Herbalife was approached by the Food and Drug Administration, it immediately took action to allay any fears that its products contained even minute amounts of possibly harmful materials. In the context of these hearings and the heightened scrutiny of Herbalife resulting therefrom, Herbalife, as always, remains open to any comments or suggestions by federal regulatory bodies. As it believes is proper, Herbalife stands ready to work with those agencies to correct perceived problems and/or to initiate actions in keeping with its public responsibility as the preeminent weight control program in America.

Obesity

Obesity -- defined in general as occurring when an individual is 30 or more pounds heavier than the norm for his or her height and bone structure -- is a daily tragedy for millions of Americans. Those who have not suffered this health problem, for indeed it is a health problem that contributes significantly to disease and mortality, can only imagine the constant frustration, despair and anguish that obesity creates. Few care to be fat, but the prevalence of sedentary lifestyles and the profusion of highly caloric foods inevitably leads many to become obese.

The continued problem of obesity, despite its serious health consequences, despite the numerous, sometimes drastic medical treatments to control it and despite the accepted wisdom that more exercise and fewer calories will defeat it, suggests that other, safe and convenient, methods are appropriate and desirable. The Herbalife nutritional program delivers such a method, as demonstrated by its extraordinary successes. The program provides a safe, effective and convenient process for weight loss and maintenance. Indeed, well over one million people have lost weight, the vast majority of whom have maintained their loss using the Herbalife program.

Herbalife is committed to the proposition that Americans can lose weight safely under a properly formulated nutritional program. Quick and consistent weight loss is widely recognized as a powerful motivating factor in the battle against obesity. This is plainly illustrated by the hundreds of thousands of people who have given up their hopes of weight control when they tried to lose weight on their own -- without the benefit of a balanced pre-formulated program -- and saw no progress. The

Herbalife program provides early weight loss and safe, successful continued weight loss, as its hundreds of thousands of proponents will attest. We believe that experience has demonstrated that medical intervention and unprogrammed self-help cannot address the problems of obesity with the same success or with the same audience as a relatively inexpensive pre-formulated nutritional program. Moreover, we believe that Herbalife has shown, by its success, that its position in the marketplace and in the fight against obesity is proper and deserved.

Transient Effects Due To Diet Change

One of the Subcommittee's primary concerns was the appearance of transient effects, such as headaches, lassitude, nausea, constipation or diarrhea, that sometimes occur after beginning the Herbalife program. As with any radical change in diet, a dieter switching to Herbalife from conventional foods may suffer some transient effects while the body adjusts to its new reduced calorie diet. Those effects reflect the body's adjustment to new, reduced, quantities of foods, to new foods or away from the types of foods previously eaten.

For example, someone accustomed to drinking many cups of coffee a day with sugar may find that he or she suffers from headaches -- a symptom of caffeine withdrawal -- or some weakness from no longer having a sugar-induced energy "high." Or, one may suffer from temporary constipation while the intestine adjusts to less bulk and smaller amounts of more nutritionally dense foods.

Also, because many people on the Herbalife program drink quantities of milk for the first time since childhood, some may suffer minor gastric distress or diarrhea because, in the intervening years, they may have developed a lactose intolerance. In short, when diet is changed radically -- with concomitant weight loss -- some people may experience minor effects that decrease and disappear as the body adjusts to a new nutritional regimen. While the Subcommittee's interest in the safety of food supplement products is laudable and proper, these transient effects do not warrant the concern and emphasis the Subcommittee seemed to place on them. The effects are minor; they are transient; and when they disappear the dieter feels well and still loses weight.

The Deaths Alleged to be Associated With Herbalife

This matter was raised for the Subcommittee by its staff in a manner that only can be described as a conclusory accusation, and Herbalife frankly believes that the Subcommittee has been ill-served. There have been absolutely no medical, legal, pathological or other findings whatever by competent authorities that link Herbalife to any deaths. Of the five claims that were inserted into the record by the Subcommittee staff, all are asserted by parties interested in a financial recovery from Herbalife and none has been demonstrated to have any validity. Indeed, upon the Subcommittee's request, the Commissioner of the Food and Drug Administration, a pathologist who has conducted in excess of 2,000 autopsies, impartially examined the clinical records and autopsy reports of the cases which alleged Herbalife involvement. He testified that, in his opinion, there was no evidence that established an absolute cause and effect relation between the deaths and Herbalife. (Tr. 47, May 15, 1985). Similarly, Herbalife's review of the materials in its possession also shows that there is no medical or legal nexus connecting Herbalife's products to the deaths inserted into the record by the Subcommittee staff.

To the contrary, the health history of Herbalife's nutritional products is exemplary. Rather than concentrating on unproved and unprovable allegations by parties who are interested in obtaining a financial recovery against Herbalife, the Subcommittee should look at the health benefits and successful use of Herbalife's weight loss products. More than 10 billion portions of Herbalife diet foods have been consumed over the past five years. More than 1,000,000 people have used Herbalife. In that time and from that number, the company has received less than 30 written complaints. As a statistical matter, complaints from less than three one-thousandths of one percent (0.0003%) of customers are not of significance. Furthermore, less than 1/10 of 1% of Herbalife consumers have sought refunds of the cost of the product under the company's "money-back" guarantee. As a practical matter, it would be hard to find a restaurant or chain of restaurants in this country that has served more than 10 billion food portions to over a million people with only 30 complaints. Herbalife submits that it is these numbers -- together with the unquestioning devotion of satisfied Herbalife users -- that attests to Herbalife's safety and efficacy.

Herbalife Is Not A Very Low Calorie Diet

Much public concern has been sparked by the potentially serious health problems associated with Very Low Calorie Diets (VLCD), particularly in light of real dangers to health caused by the liquid protein diets of recent years. Herbalife concurs that very low calorie diets, on the order of 500 or less calories a day, *are* potentially dangerous and should be undertaken only while under a physician's supervision. Yet, it cannot be stressed too strongly, Herbalife is *not* a Very Low Calorie Diet. The Herbalife nutritional program provides 1,000 or more calories a day in two Herbalife product meals and one recommended balanced meal from the seven basic food groups. The program thus accomplishes its dual goals of safely reducing caloric intake in a controlled manner, while providing at least 100% of the recommended daily allowance ("RDA") of protein, vitamins and minerals.

Moreover, weight loss is effected without the nutritional deficiencies that characterize VLCDs. Preliminary results from a long-term prospective study underway in conjunction with the University of California at San Diego show *normal* blood serum mineral levels of iron, zinc, copper, magnesium, potassium and calcium in seven individuals who have used the Herbalife nutritional program for one to four years, a period sufficient to detect the presence of long-term nutritional deficiencies. The concerns that rightly are focused on VLCDs simply do not apply to the Herbalife program, which is not a VLCD and can be used safely and properly without medical supervision.

Clinical Testing

The Subcommittee questioned Mr. Hughes and Dr. Katzin at length regarding clinical tests that have been or are being performed on Herbalife products and components. First, it should be noted that because Herbalife products are classified as foods, as a matter of law the FDA does not require clinical testing, as it would in the case of drugs. Second, until now, as a matter of public responsibility the issue of clinical testing of Herbalife products simply has not arisen because the products have been used extensively and only a statistically insignificant number of complaints have been received. Moreover, each of the individual components of Herbalife's weight control products has been the subject of scientific scrutiny. Although not conducted by Herbalife these studies appear throughout the scientific literature. Herbalife does not believe, and to its knowledge, the FDA does not deem, any component of Herbalife's weight control products to be unsafe or harmful.

As a further matter of importance with regard to testing, the issue of clinical product testing should be considered by the Subcommittee in context, because it is well recognized that clinical tests are not the only yardstick of safety. The Food and Drug Act requires testing of drugs because, as a matter of public health, it is deemed crucial to test new drug substances in laboratory animals, and ultimately in people, in controlled conditions to determine safety and efficacy. The results of these tests are then extrapolated from the small experimental group to apply to the larger target group, or to the population at large. If the risks of danger from a new drug appear unacceptably large in relation to the target group or to the population, the drug may be deemed unsafe and may not be produced or marketed. In this manner clinical tests are used to predict the possibility of otherwise unforeseen dangers before a drug is distributed to the population at large.

Because Herbalife nutritional products are foods, not drugs, the FDA law does not require such preliminary clinical testing. Further, as a practical matter, the predictive function of clinical tests is irrelevant because Herbalife's nutritional products already have been distributed to the population at large and used by it. Over 10 billion portions of Herbalife foods have been consumed by over 1 million Herbalife users and, as noted earlier, Herbalife has received less than 30 complaints, 0.0003% of its consumers.

In determining the safety of food products or drugs, it is clear that larger sample groups give more accurate results from which to extrapolate. In this case, there is an extremely accurate result from an extremely large user population. Predictions from clinical tests are not needed where, as here, results from actual and extensive use already exist. Nevertheless, Herbalife has undertaken retrospective and long-term prospective tests on the Herbalife user population to show the long-term safety and usefulness of Herbalife in controlled experiments or against the normal values of the population. The partial results of those tests have indicated significant weight loss for the study group, maintained over one year, with normal blood serum mineral levels, indicating no long-term nutritional deficiencies. (See Hearing Testimony of Dr. David B. Katzin). Further results are expected to be available in 60-90 days.

Labeling

Many of the Subcommittee's concerns seemed to focus on questions of labeling. In particular, concern was expressed that Herbalife's NRG -- Nature's Raw Guarana, and APR -- Arthritis Pain Reliever were mislabeled because the NRG label did not list caffeine as an ingredient and because the APR label made medical claims while ostensibly being marketed as a food. Although each NRG tablet contains only approximately 3% - 5% of naturally-occurring caffeine, concerns over possible consumption by individuals who are ultra-sensitive to caffeine have prompted Herbalife to announce that it will voluntarily relabel NRG to reflect its caffeine content. With regard to the APR label and medical claims, the Subcommittee appears to have functioned under the misconception that APR was treated by Herbalife and the FDA as a food. That is incorrect. APR is treated as a drug by Herbalife and is so listed with and treated by the FDA. Any such concerns regarding APR are simply misplaced.

During the hearings, Senator Roth expressed his concern that the Herbalife weight control program might be misused by children, pregnant or lactating women, or persons under a doctor's care. Herbalife believes that its products are safe for pregnant or lactating women, as well as children, since Herbalife weight control products also may be used to gain weight. Herbalife also believes that children and pregnant women are unlikely to begin a weight reduction program without consulting a physician. However, as a voluntary measure to allay concerns that Herbalife products may be misused, Herbalife has changed its Formula I product label to include a cautionary statement that anyone considering a weight control program (especially children and pregnant or lactating women), should consult with a physician.

As is discussed more fully within in reference to Herbalife's 1982 Career Book, at an early point in Herbalife's corporate existence Herbalife apparently presented what it now readily acknowledges were some confusing labeling claims. Although such claims were promptly removed, some of Herbalife's detractors who testified before the Subcommittee based their criticisms on these old, disavowed claims. Herbalife welcomes a scientific discourse with these specialists, but encourages them not to perpetuate claims the company itself has withdrawn. Herbalife also presently is undertaking a review of all its products and labels and is ready and willing to discuss proposed changes with the appropriate regulatory agencies to ensure its compliance with all federal rules and regulations.

Marketing

Another topic of concern was the past, inadvertent publication of potentially inappropriate health claims in Herbalife's marketing materials and meetings. Herbalife takes seriously its responsibility to comply with all regulations regarding advertising and product claims. Herbalife recognizes that, as a result of some past marketing activities, it has some present difficulty, despite strenuous company efforts, in making absolutely sure that its distributors or users do not make improper claims on its behalf. To this end, a number of measures to assure proper compliance are in place. Further, pursuant to concerns expressed by the Subcommittee, Herbalife presently is formulating additional measures to ensure even more complete compliance.

One element of Herbalife's marketing strategy is the use of testimonials about Herbalife weight control products by consumers who have achieved significant weight loss while using the product. Often, these consumers had suffered from other ailments that may have been attributable to their obese condition. As a result of their weight loss, some of these other health problems -- such as back pain or high blood pressure -- have been alleviated. Herbalife always has disclaimed responsibility for anything other than weight loss (or gain where appropriate) as a result of use of the weight control products. Nevertheless, the enthusiasm of some of these consumers, while stating their testimonials during Herbalife sales meetings, has led them to make inappropriate health claims not sanctioned by Herbalife. After some initial live television broadcasts in which such claims were aired, notwithstanding Herbalife's express direction not to make claims for anything but weight loss (or gain), Herbalife changed its television broadcast format. Now, the testimonial section of a live satellite broadcast sales meeting is "blacked out." Later, the videotaped testimonials are edited to exclude any health claims before they are permitted to be aired to the public.

Herbalife has a set of strict rules that apply to distributor conduct. Making health or medical claims for Herbalife's products is expressly forbidden. If Herbalife determines that a distributor has violated its rules by making medical claims, Herbalife imposes sanctions upon that distributor up to and including his or her termination from Herbalife. Herbalife is in the process of devising even stricter directives for its distributors to further prevent the dissemination of improper, inaccurate or outdated Herbalife sales material. And, as noted earlier, Herbalife is reviewing and revising its labeling, claims, and sales material.

The 1982 Official Herbalife Career Book

During the hearings. Herbalife was criticized for claims that appeared in its 1982 Official Herbalife Career Book. The 1982 Career Book contains what may appear to be Herbalife's claims for the properties of certain herbs but, in point of fact, Herbalife never intended those health claims to be construed as its own and so stated in the Career Book itself. Their inclusion in the Career Book was the result of an innocent misunderstanding regarding the taking of quotations out of the context of their original sources. Herbalife included lists of claims for various herbs in an effort to demonstrate that a particular herbal property, for example, appetite suppression, was recognized in scientific and popular literature. The author of the Career Book thought, incorrectly, that a quotation from another work had to be published in its entirety, and that ellipses indicating material removed and not relied upon could not be used. Accordingly, entire quotations, although partially inapplicable but including the desired appetite suppression claims, were set out in full on a page separate from Herbalife's own claims.

With the advantage of hindsight and greater experience, Herbalife fully acknowledges that its publication of those health claims -- even though not intended to be claims for Herbalife products -- was mistaken. Upon learning of its error, Herbalife issued a new Career Book that included no such inappropriate claims. Herbalife further has instructed its distributors not to use, or assert, claims from the 1982 Career Book. This unfortunate error, made without any intention to endorse health claims for herbs, is perhaps an illustration of an early, innocent mistake now laid at the door of a larger, more mature organization. Criticism of Herbalife now for its error then, particularly since those claims repeatedly have been repudiated, is plainly unfair and inappropriate. Herbalife does not now make such claims, never intended to make those claims, and it suspends and/or terminates those distributors who make such claims. Herbalife always has been willing to discuss its obligations with the appropriate regulatory authorities, but it takes issue with the use of its outdated, concededly inappropriate, repudiated and innocently authored materials to brand it as being unconcerned with regulatory compliance.

Product Efficacy and Maintenance of Weight Loss

In Dr. David Katzin's statement to the Subcommittee, he presented the preliminary results of a retrospective study of Herbalife users. Of 428 persons whose weight history was taken in the initial portion of the study, 381, or 88%, lost weight with the Herbalife program. The remaining 12% may have gained weight either because they so desired it or because they may have used the product to maintain their weight. Katzin's study shows that of the 428 individuals, 417, or 97.4% maintained their weight after a year or more. Katzin's study shows that of the 381 persons who lost weight, 131 lost 30 or more pounds and 39 persons lost 50 or more pounds. These impressive figures are in accord with the subjective impressions of Herbalife distributors around the country who find that Herbalife users often achieve significant weight loss that is maintained, in most cases, for a year or more. Because fewer than 10% of individuals in the general population who lose a significant amount of weight maintain that weight loss for more than a year, the results of

Herbalife's study are extremely encouraging. If these figures are borne out in the entire retrospective study, this data alone would be sufficient to conclude that the Herbalife nutritional program represents an effective weight control technique.

Conclusion

Herbalife hopes that this supplemental statement has mitigated the concerns raised by the Subcommittee by demonstrating that Herbalife products are safe and useful in the control of weight problems and are not quack nostrums whose effects are dangerous, whose methods are fraudulent or whose results are illusory. Unlike diet pills which are claimed to dream away fat, or earrings that are claimed to suppress appetite, the Herbalife nutritional program provides or includes preformulated, balanced, and nutritionally dense foods in a calorie-controlled program that allows significant weight loss and weight control. It is not a very low calorie diet. The Herbalife program has allowed hundreds of thousands of formerly overweight and obese people to change their lives by losing weight safely. Herbalife is committed to the fight for proper nutrition and against obesity. It recognizes that its preeminence as the leading weight control program in America gives it a special responsibility to the public. Leaving its early actions and growing pains in the past, Herbalife is ready and willing to discuss and undertake any appropriate action to ensure its continuing compliance with all federal regulations and its provision to Herbalife users of safe, useful and convenient products.

Herbalife endorses Senator Glenn's statement in these hearings: "[T]he U.S. Government has no business playing Big Brother -- and adult Americans should have the right to choose any diet plan they wish, so long as the advertising claims of those plans are not fraudulent, federal rules and regulations are being adhered to, and the products do not constitute a public health hazard." Herbalife wishes to emphasize that its advertising claims are not fraudulent, that it has taken, and is taking, steps to ensure that none of its distributors makes fraudulent claims, and that it presently adheres to and intends to continue to adhere to all relevant federal rules and regulations. Most importantly, it is clear beyond peradventure that Herbalife is proven effective and safe.

RESPONSES TO WRITTEN QUESTIONS SUBMITTED BY SENATOR GLENN

QUESTION 1: In Mr. Hughes' initial testimony, he stated that the woman who died in Florida after a serious illness did not die as a result of using Herbalife products. Also, in testimony presented by Dr. Katzin, it was stated that people under the care of a physician -- victims of strokes, heart attacks, or pregnant women -- should not use the Herbalife products without medical supervision. Why, then, were these products sold to the woman in Florida? Shouldn't the question of her health have been raised by the distributor before the sale.?

RESPONSE: It should first be made clear that Herbalife distributors are not physicians and do not purport to tender medical advice or render medical care. Indeed, Herbalife distributors are strongly and continuously warned not to make medical claims for Herbalife products. They are, in fact, disciplined if they are found to have made medical claims. The only function of Herbalife distributors is to sell Herbalife products and to check regularly on the weight loss (or gain in appropriate cases) of Herbalife customers. They are not trained or expected to take medical histories or give medical diagnosis.

In this context, Mr. Hughes referred in his opening statement to the death of Catherine Tyson. Mrs. Tyson was 45 years old; she weighed approximately 300 pounds, and had apparently suffered at least one stroke some years earlier. She was under the care of a physician who had repeatedly told her that she must lose weight and who had repeatedly placed her on weight reduction plans -- without any success.

It is Herbalife's firm belief that if Mrs. Tyson had properly used the product as instructed and had not willfully refused to follow the product directions and the distributors' instructions, the Herbalife products would have produced a safe and effective weight loss. Instead, after her Herbalife distributors gave her an initial supply of Herbalife Formula 1 through 4 and explained how the products should be used, Mrs. Tyson refused to follow the product directions, refused to eat solid food -- which her distributors even prepared for her on their visits to check her progress -- refused to take her medications in the doses she had been prescribed and refused to consult with her doctor or seek the advice of another doctor.

The Herbalife distributors gave nutritional products to a person who plainly needed to lose weight and who was under the care of a physician who had repeatedly instructed her to lose weight and who had put her on weight reduction plans with no prior success. Her distributors repeatedly attempted -- during their visits to check on her progress -- to have her follow the product directions, to have her take the medications in the doses prescribed by her physician and to have her consult with her physician or another physician recommended by the local health department. In each instance Mrs. Tyson either refused to cooperate with their requests or falsely represented that she had complied with their requests. Inasmuch as the initial sale had already been made, it is difficult to imagine what further actions the Herbalife distributors could take. Plainly, they could not take away the products that Mrs. Tyson had purchased. Just as plainly, they could not force an emancipated, competent adult to eat the meals they prepared for her, to take her prescribed medication or to consult her doctor if she refused to do so. As with any foods or weight control programs, there must be an assumption that the purchaser is rational and will not knowingly and willfully misuse the products or act in a manner that is incompatible with the actions of a reasonable consumer. Mr. Hughes' statement is not controverted -- there is no proven or provable cause and effect relationship between Mrs. Tyson's death and the use of Herbalife products. Rather, her refusal to eat solid food, to follow product instructions, to take her prescribed medications in the proper dosages and to consult her physician, as she had been requested to do, would seem to be more likely reasons for her demise, particularly in light of the safe and effective use of Herbalife foods by over a million other consumers.

QUESTION 2: In cases where prospective customers are seriously ill or at risk, do distributors make an effort to explain the possible health problems and hazards that can occur as a result of utilizing low calorie diets such as Herbalife? Would labels on Herbalife products be a mechanism for informing consumers about these possible health complications?

RESPONSE: Because of the concern expressed by the Subcommittee that some individuals could be harmed by following any weight reduction production, Herbalife has added to its Formula I label the following cautionary statement:

> When considering a weight control program it is advisable (especially for children and pregnant or lactating women) to consult with a physician.

Moreover, as indicated in Mr. Hughes' testimony, Herbalife has added to its N-R-G label the following description of caffeine as an ingredient:

> Guarana contains approximately 4% of naturally-occurring caffeine.

Herbalife hopes that the addition of this information will help to allay the concerns expressed by the Subcommittee, and will address whatever problem is perceived with regard to medical supervision of dieters.

Herbalife cannot overemphasize that the Herbalife Weight Control Program is not a Very Low Calorie Diet ("VLCD"). A VLCD supplies 500 or fewer calories per day. Taken as directed, the Herbalife Weight Control Program supplies in excess of 1000 calories per day. Distributors are instructed to explain the proper use of Herbalife products, which includes daily consumption of a well-balanced meal of 800-1000 calories in addition to two Herbalife shakes per day.

It can only be assumed that prospective customers are aware of a weight problem and want to take action to alleviate it. Often, prospective customers begin the Herbalife program because they have been told by their physicians that they must lose weight. As a matter of course, it should be expected that a "seriously ill" or "at risk" prospective customer is already under medical care or instruction and would not undertake a significant dietary change without the approval of his or her physician.

Herbalife's label change, which has been implemented and will take effect nationwide once the current supplies of previously labelled products are depleted, is an effort to make more clear the common-sense requirement that an ill or "at risk" person undertake medical consultation before beginning a weight control program. Of course, as with any program or type of food, distributors cannot prevent intentional misuse of a product and willful refusal to follow directions or instructions.

Herbalife distributors are taught to follow the progress of each customer and assist in the weight loss process by describing the program and providing instructions for its use. Beyond that, it is difficult to imagine what more Herbalife, or any of its numerous competitors, could do.

STATEMENT

OF

DAVID B. KATZIN, M.D., Ph.D.

BEFORE

THE

SENATE PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS

CONCERNING

WEIGHT REDUCTION PRODUCTS

ON

MAY 15, 1985

Chairman Roth and Members of the Permanent Subcommittee on Investigations:

My name is David B. Katzin. I am a scientist and a physician presently in private practice in Los Angeles. Over the past five years, I have personally attended to well over one thousand individuals, many of them for weight control or weight-related problems.

As you well know, obesity is a major problem in the United States today. I personally would not classify obesity as a disease but rather as a result of changing lifestyles which include decreased activity and an increased intake of highly caloric foods. However, as the Select Committee on Nutrition on Human Needs has pointed out, obesity is a major contributor to disease and mortality in the United States and thus demands immediate attention. (1)

As a physician who has dealt personally with many of these patients, let me further state that obesity is significant not only in the way it affects disease patterns but also in the way it affects individuals, their lives and their families. Those of us who have never had a weight problem cannot begin to imagine the frustration, despair and anguish that obesity creates. In addition, obesity drastically affects an individual's self-confidence and decreases his earning power in the marketplace. For these reasons obese individuals desperately search for successful weight loss programs. Unfortunately, few of even the most well-researched and well-supervised programs, be they medical or otherwise, succeed. As a general rule, fewer than 10% of individuals who lose a substantial amount of weight maintain it for more than a year.

My colleagues in the medical community have been as unsuccessful in helping people lose weight as have lay organizations. More than one study has indicated that lay organizations are more effective than medically supervised programs in helping people lose weight. The poor success the medical community has had in treating obesity has resulted in the creation of a panoply of heroic and potentially dangerous treatments, including the use of amphetamines, hormone injections, jaw wiring and intestinal bypass operations. Even so, the effectiveness of the medical approach in controlling obesity is dismal. This has led Dr. Albert Stunkard, M.D., of the University of Pennsylvania to state, "the most promising new methods for controlling obesity seem to lie almost entirely outside the medical profession." (2)

It is against this background that the Herbalife nutritional program was created approximately six years ago. There appears to be considerable confusion as to precisely what the Herbalife nutritional program is, and I feel much of the criticism levelled against it arises out of this confusion. Let me attempt to set the record straight.

The Herbalife nutritional program is nothing more than sound basic nutrition. It is a combination of the macronutrients protein, carbohydrates and fat, and the essential micronutrients vitamins and minerals necessary for good health. When used in combination with a specified meal plan which includes a balanced meal from the seven basic food groups, a one-thousand calorie weight-reducing diet can be achieved.

This committee has heard considerable testimony on the benefits and dangers of very low calorie diets. (3) These are diets which contain less than 500 calories and consist exclusively of formula drinks. One such diet is the Cambridge diet. Other such diets include medically supervised diets like Optifast and Medfast. These diets can be potentially extremely dangerous and must, under all circumstances, be supervised medically. Even then serious side effects may occur; however, medical supervision reduces the risk of prolonged or permanent complications. (4)

HERBALIFE IS NOT A VERY LOW CALORIE DIET. Please refer to the accompanying figure for the differences. In particular Herbalife does not have 500 calories, it has 1,000 or more calories. In addition, the balance of protein, carbohydrate and fat is entirely different. Very low calorie diets are deficient in potassium, whereas the Herbalife nutritional program contains adequate potassium according to RDA recommendations. In addition, the Herbalife nutritional program contains a balance of vitamins and minerals which meet or minimally exceed the RDAs for these nutrients.

I must respectfully disagree with some of my esteemed colleagues who spoke yesterday when they stated that a 1200 calorie diet plan designed according to basic nutritional recommendations was adequate for weight loss. As you can further see in the accompanying diagram, a 1,200-calorie diet based on nutrient proportions recommended by the American Dietetic Association, which closely approximates what the average American eats under the best of circumstances, may lead to deficiencies in protein, as well as many vitamins and minerals. Such a diet, unless supplemented with protein and a vitamin-mineral tablet would certainly lead to deficiencies and must be considered unsafe. In addition, diets such as these have notoriously poor compliance precisely because there are minor nutrient deficiencies which lead to cravings and emotional lability. Individuals will naturally discontinue such a diet and quickly regain any weight they may have lost.

I would certainly agree, however, with my colleagues in stating that weight loss is ultimately a matter of taking in fewer calories than you burn up. However, for an individual to continue to do this over the long run the nutritional program must be safe, effective and above all, convenient. I believe the Herbalife nutritional program is all of these and therefore succeeds where so many of the other programs fail.

Let me address the issue of safety. There are several ways to determine the safety of a nutritional program. One way is to evaluate the components of the program theoretically and predict on that basis whether problems might develop. The Herbalife program clearly is safe by this standard for all of the reasons noted above.

The ultimate test of the safety (and effectiveness) of a product is to test the product in the field. By this standard, Herbalife is also safe. Literally billions of portions of the product have been served to more than a million individuals with only minimal transient side effects. I know of no other nutritional program which has been used as widely as the Herbalife program or as safely.

A third way of evaluating the safety of a program is through laboratory testing. A major concern in the long- term use of a program like the Herbalife one is the development of deficiencies of serum electrolytes and minerals. As part of a long-term, prospective study, presently being carried out at the University of California - San Diego, we have evaluated seven Herbalife consumers for nutritional deficiencies. These individuals have used the Herbalife nutritional program for one to four years, certainly enough time to develop nutrional deficiencies. Complete blood profiles including serum electrolytes and serum minerals were obtained. As you can see in the accompanying chart, there were no deficiencies of serum potassium, magnesium, calcium, iron, zinc and copper. In fact, as the next table indicates, there were no abnormal findings in the blood of these patients whatsoever. From this we may conclude that the Herbalife nutritional program is safe. Further detailed reports from the University study will be available within 60-90 days.

Let me now turn to the issue of effectiveness. As part of a retrospective study on the entire Herbalife consumer database, the following initial results have been obtained. The accompanying graphs show the weight loss distribution in a sample of Herbalife individuals who have used the product for more than one year. The total number of individuals in the study is 428. Of these, 381 or approximately 88% lost weight while using the products. The graph shows the distribution of weight loss in pounds on the bottom scale and the number of individuals in each category on the left-hand scale. If you look toward the left of the graph you will notice that more than 30% of the individuals in this study lost 30 or more pounds. As you will recall from yesterday's testimony, 30 pounds represents the cutoff point for obesity in an individual weighing 150 pounds. Obviously, this program has allowed many obese individuals to lose weight.

The question may be raised: why didn't all the individuals lose 30 or more pounds? The answer is because they did not need to lose this much weight. As you can see in the next graph, 97% of individuals are maintaining their weight. Clearly, the Herbalife program is effective for individuals who need to lose anywhere from 5 pounds to 50 or more pounds. I would like to add that these individuals have maintained their weight loss for more than one year, some longer. None of the individuals in the group sampled regained their weight. Since, as we noted above, less than 10% of individuals who lose a significant amount of weight maintain that weight loss for more than a year, the results of this study are extremely encouraging. Clearly, the Herbalife nutritional program represents an effective weight control technique.

I would like to summarize my statement as follows. Obesity is a major problem in the United States today with many physical, emotional and social ramifications. The treatment of obesity is primarily a lay problem, not a medical one, and must be solidly grounded in a good nutritional program that gives the individual fewer calories than he consumes. The Herbalife nutritional program is such a program. It is safe and effective when the recommendations made by the company are followed. The Herbalife nutritional program is a low-calorie nutritional alternative to complicated and potentially deficient diet plans. It is not a very low calorie diet and should not be confused with one. Because of this it is safe for the vast majority of individuals who need to lose weight.

Thank you for allowing me to appear before this Committee. I congratulate the Senator in examining the complicated, confusing and often misleading field of weight loss. I will be pleased to assist this Committee in any way I can. Thank you.

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3. Kreitzman, S., "Safety and Effectiveness of Weight Reduction Using a Very-Low-Calorie Formulated Food." Archives of Internal Medicine, Vol. 144, No. 4, pp. 747-750, 1984.

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M.D.,	University of California, Los Angeles - School of Medicine, June 1980.
Ph.D.,	Physiology. University of California, Los Angeles, March 1975.
B.S.	Magna cum laude, Chemistry. University of Chicago, June 1967.

ACADEMIC HONORS AND AWARDS:

American Heart Association - Greater Los Angeles Affiliate, Senior Research Fellowship. University of California, Los Angeles, 1975-76.

National Institute of Health Research Training Grant. UCLA, 1971-75.

Hertz Foundation Scholarship (honorable mention), 1967.

National Science Foundation Research Award. University of Chicago, 1966.

National Science Foundation Research Award. Wesleyan College, 1961.

PROFESSIONAL EXPERIENCE:

Medical Director, Westwood Medical Group, Los Angeles, California, 1983 - present.

Medical Director, Beverly Detox, Los Angeles, California, 1983 - present.

Attending Physician, Bresler Medical Group, Los Angeles, California, 1982-83.

Attending Physician, Hoover Medical Group, Los Angeles, California, 1981-82.

Resident Physician, Internal Medicine, Cedars-Sinai Medical Center, Los Angeles, California, 1980-81.

Post-Doctoral Research Fellow, Department of Physiology, UCLA, 1975-76.

Adjunct Lecturer, Department of Physiology, UCLA, 1972-76.

Research Assistant, Department of Physiology, UCLA, 1971-75.

Teaching Assistant, Department of Physiology, UCLA, 1970-75.

Teaching Assistant, Department of Molecular Biology, UCLA, 1969-70.

Research Chemist, Purex Corporation, Wilmington, California, 1968-69.

Research Assistant, Department of Physical Chemistry, University of Chicago, 1965-67.

PROFESSIONAL SOCIETIES:

American Association for the Advancement of Science

American Medical Association

American College of General Practice

American College of Sports Physicians

Los Angeles County Medical Association

HOSPITAL AFFILIATIONS:

French Hospital of Los Angeles

Brotman Memorial Hospital, Los Angeles, California

PUBLICATIONS:

Katzin DB and Rubinstein EH: Modulation of sinus arrhythmia in the rabbit.
Fed. Proc. 35:424 (abstr.), 1976.

Katzin DB and Rubinstein EH: Reversal of hypoxic bradycardia by halothane or midcollicular decerebration.
Am. J. Physiol. 23(1):179-84, 1976.

Katzin DB and Rubinstein EH: Vagal tachycardia: a component of the response to hypoxia.
Physiol. 18:147 (abstr.), 1975.

Katzin DB: Vagal control of heart rate during activation of the arterial baroreceptor and chemoreceptor reflexes. (Ph.D. Thesis) UCLA, 1975.

Katzin DB and Rubinstein EH: Vagal control of heart rate during hypoxia.
Proc. Soc. Exptl. Biol. Med. 147:551-557, 1974.

COMMUNITY SERVICE:

Bi-weekly lectures on health and nutrition to lay audiences in Los Angeles area, 1982 - present.

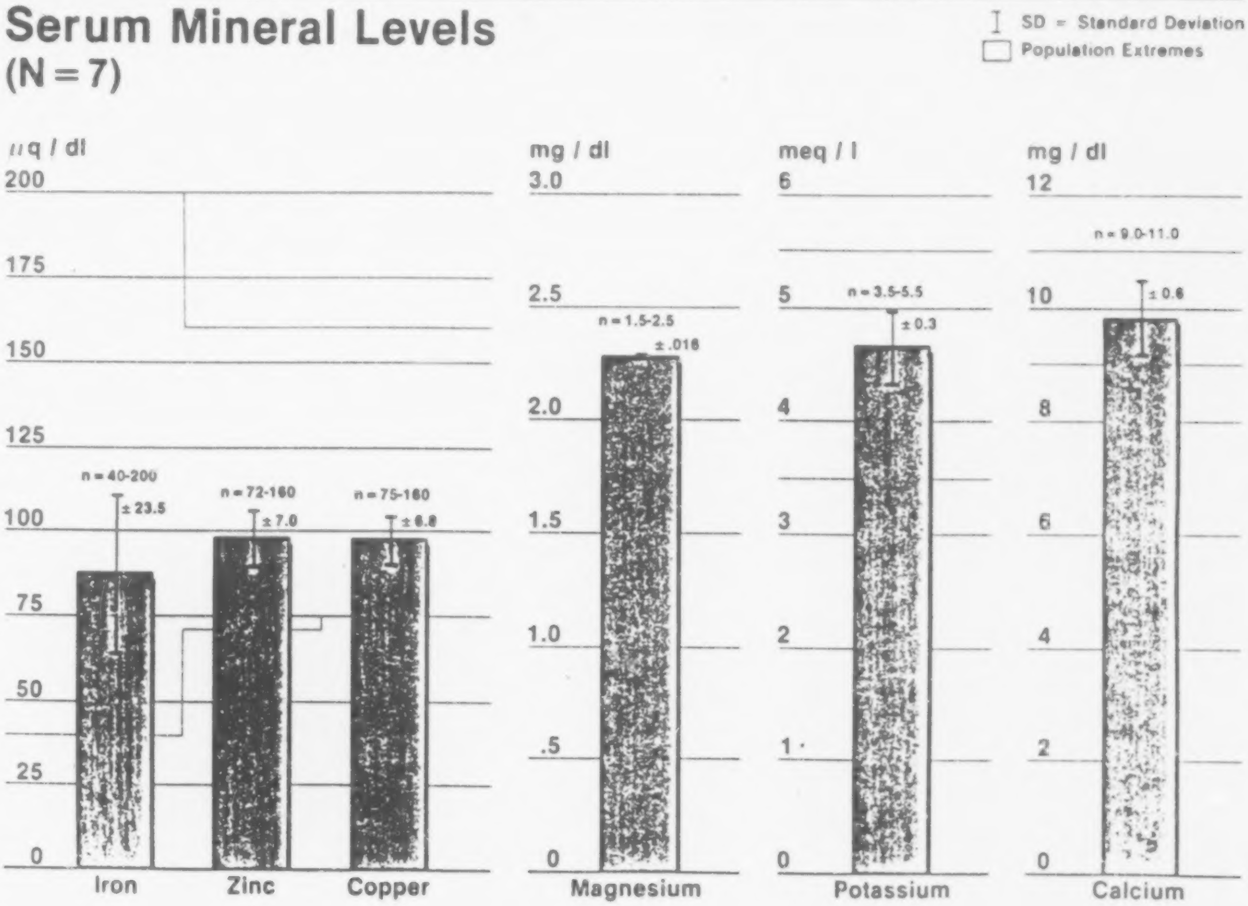
Television and radio appearances on health related issues, including KABC-TV, KTLA, CHN, KABC-talk radio and KKGO-talk radio, 1983 - present.

Nutritional consultant to REPAIR, a drug and alcohol rehabilitation program, 1984 - present.

Comparison of Herbalife, Optifast and 1200 Calorie ADA Diet

	Herbalife	Optifast	1200 Calorie ADA
Calories	1000	500	1200
Protein	75 g (30%)	80 g (65%)	30 g (10%)
Carbohydrate	150 g (60%)	40 g (30%)	150 g (50%)
Fat	11 g (10%)	3 g (5%)	53 g (40%)
Potassium	2.5 g	1.0 g	2.5 g
RDA of Vitamins and Minerals	+	?	–
RDA of Protein	+	+	?
Food	+	–	+
Long Term Safety	+	–	?

Serum Mineral Levels
(N = 7)

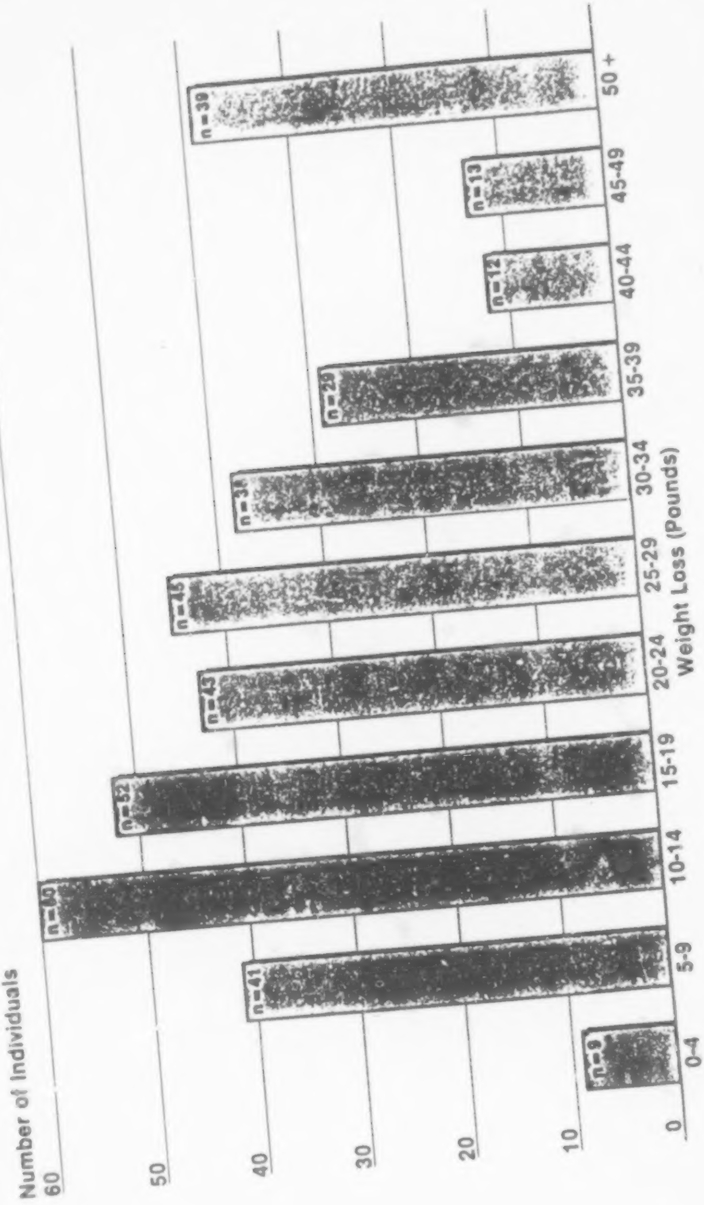


Long Term Laboratory Evaluation of Herbalife Program

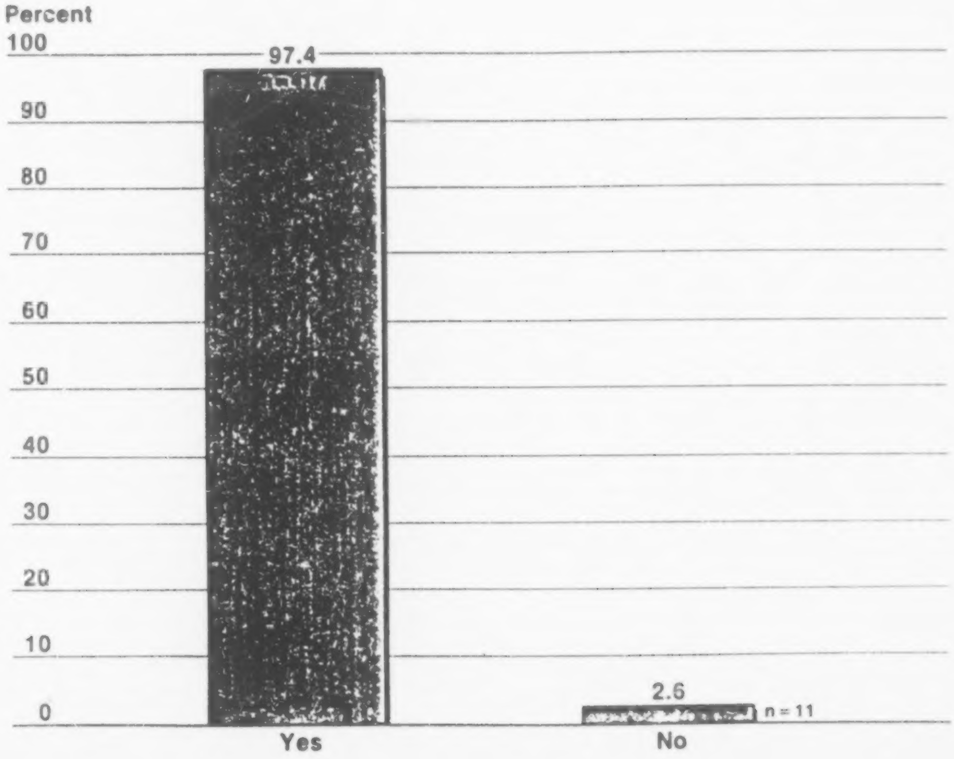
T=6 Months - 4 Years (N=7)

	Normal Serum Values	Abnormal Serum Values
Calcium	X	
Potassium	X	
Iron	X	
Copper	X	
Magnesium	X	
Hemoglobin	X	
Vitamin B_{12}	X	
Folic Acid	X	
White Blood Count	X	
Fasting Blood Glucose	X	
Liver Function	X	
Kidney Function	X	
Thyroid Function	X	
Protein	X	
Electrolytes	X	
Uric Acid	X	
Cholesterol	X	
Triglycerides	X	

Weight Loss Profile
(N = 428, N' = 381)

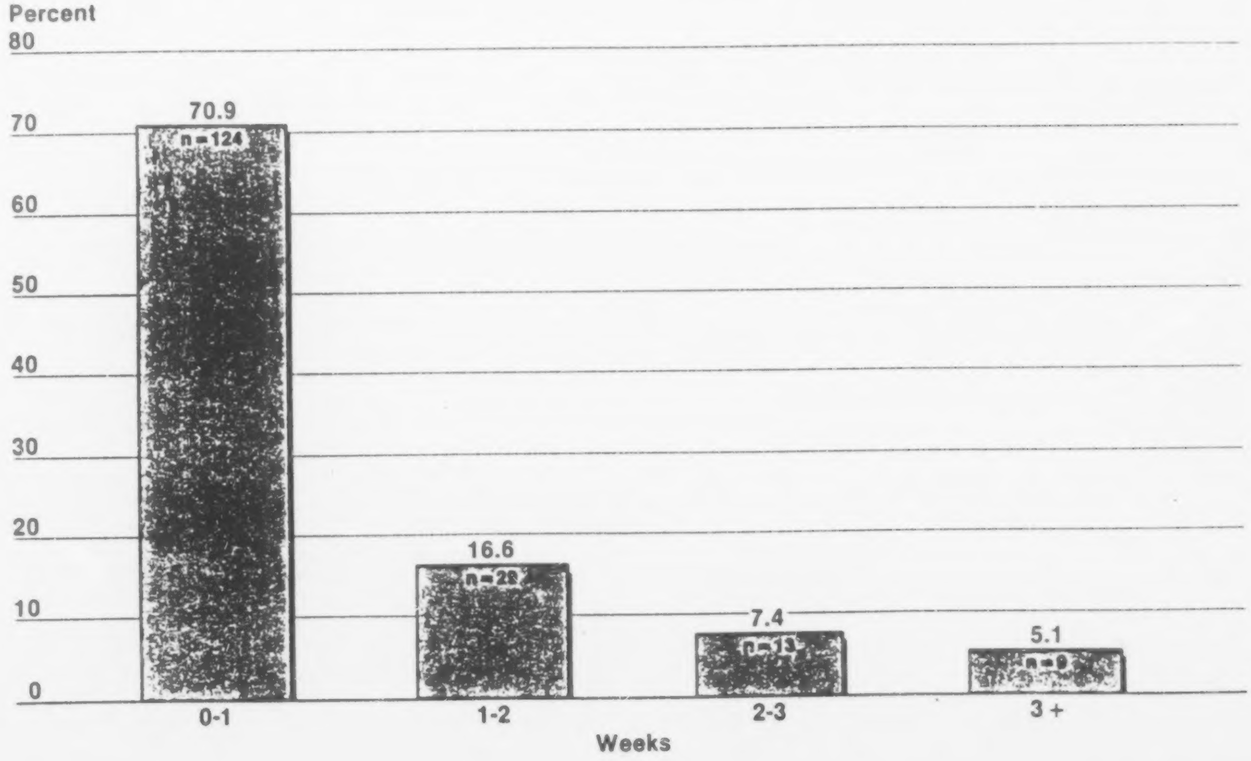


Weight Loss Maintenance
(N = 428)

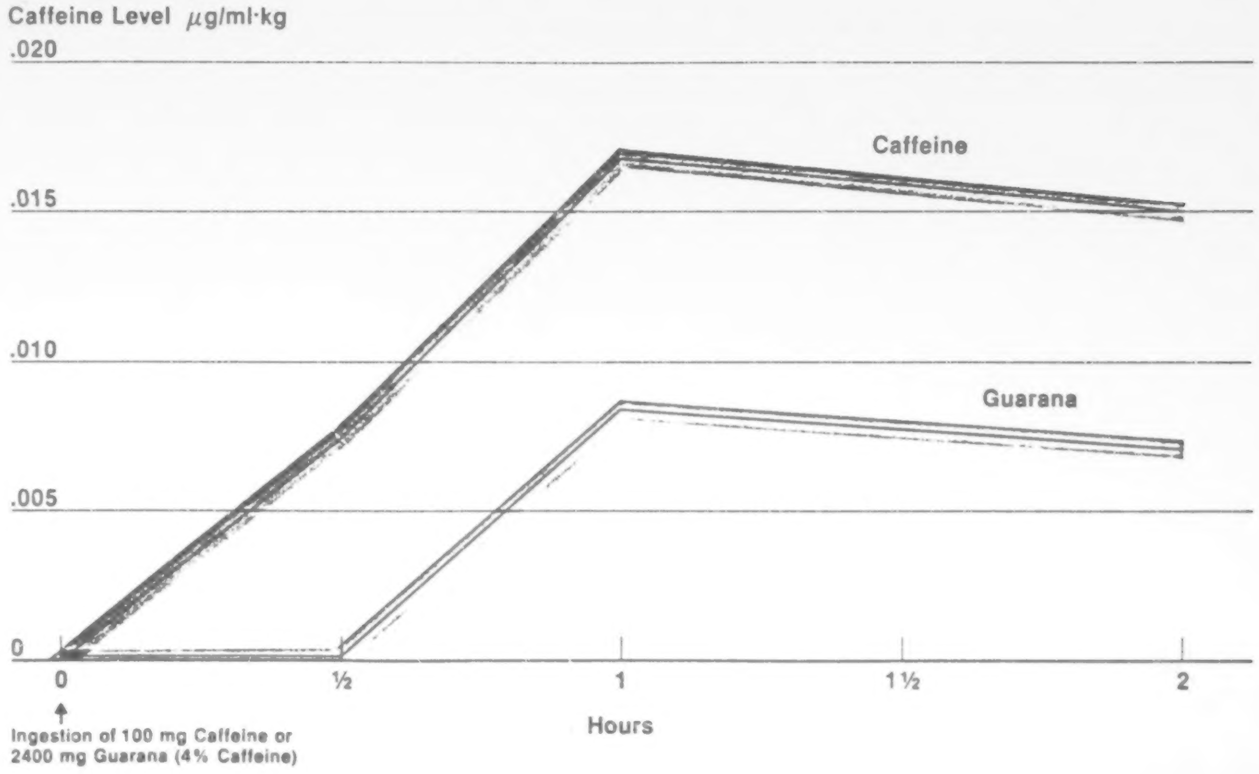


Duration of Side Effects

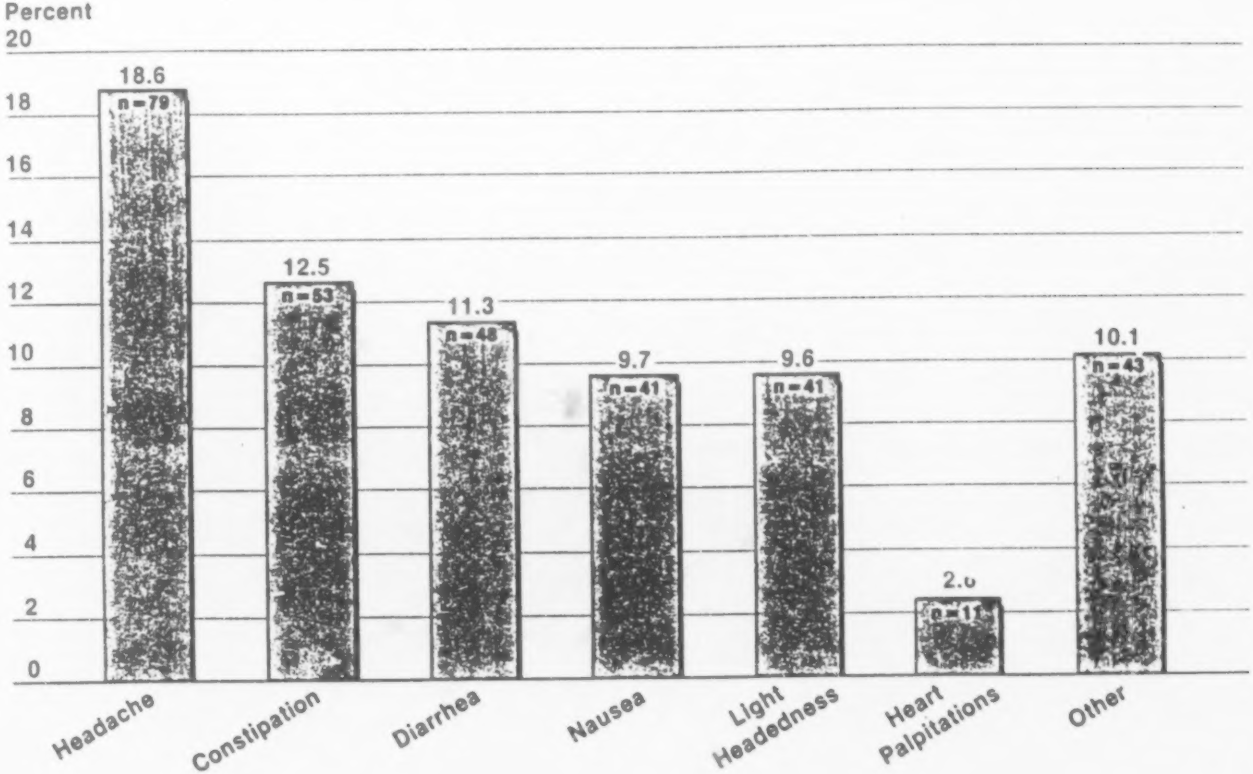
(N = 175)



Blood Levels of Caffeine (Weight Adjusted)
(N = 6)



Transient Side Effects by Category



Chairman ROTH. Gentlemen, I think we are at the conclusion——

Mr. LEVINE. Mr. Roth, may I make a response to that, if I may?

Chairman ROTH. I don't believe you are under oath.

Mr. LEVINE. I am not under oath. If a response would be in order for no other reason to tell Mr. Rudman who I am. Barry Levine. I am one of the attorneys representing Herbalife. That statement is totally irresponsible by Mr. Rinzel. Mr. Rinzel knows—surely he should have known—about every one of those deaths. If one were to look at the death pertaining to Mr. Lee, as I did yesterday after hearing about it from Mr. Shapiro's statement, I called up the New York Times. I learned from the Associated Press in a short obituary the following statement was made: "An autopsy failed to reveal the cause of death." Now Mr. Rinzel knew that yesterday and he knew that a moment ago, and to link, as he just did, the mere possibility that that death is associated with Herbalife products is irresponsible in the extreme.

Chairman ROTH. Let me——

Mr. LEVINE [interposing]. I am prepared to address each of these with the same degree of accuracy.

Chairman ROTH. Let me say you are not a witness here. You are permitted, if you want, to submit a statement for the record, but at the present time, you are not here as a witness.

Mr. LEVINE. That is quite true, Senator Roth.

Chairman ROTH. As I said, it will be appropriate for you, if you choose, to submit a statement of the type you desire to make here, but you are not a witness at this hearing, and I think the time has come to bring the hearing to a close.

The subcommittee will be in recess.

[Whereupon, at 3:02 p.m., the subcommittee adjourned to reconvene at the call of the Chair.]

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

New odd page

THE AMERICAN DIETETIC ASSOCIATION
430 NORTH MICHIGAN AVENUE, CHICAGO, ILLINOIS 60611
TELEPHONE (312) 280-5000 (312) 280-

PERM. SUBCOMMITTEE
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May 31, 1985

The Honorable William V. Roth, Jr., Chairman
Permanent Subcommittee on Investigations
Senate Governmental Affairs Committee
SR-100 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Roth:

This represents the testimony of The American Dietetic Association (ADA), the national organization for 50,000 nutrition professionals, on certain points made by witnesses at your Subcommittee's May 14-15, 1985, hearing on weight reduction products and plans. We ask that this letter be included in the published record of the hearing.

First, we would like to commend your Subcommittee for recognizing the importance of its oversight function in this area, and for providing the scientific community with an opportunity to refute claims made by various product manufacturers as a matter of public record.

Second, we thank FDA Commissioner Frank Young, M.D., Ph.D., for recommending in his testimony that people consult a physician and dietitian before embarking on any very restricted diet.

Third, we are concerned about the portion of the testimony submitted by the FTC's Bureau of Consumer Protection that deplores its lack of explicit statutory authority to take action against deceptive marketing of health care services. In light of a $25-billion-a-year health fraud industry and the recent House subcommittee recommendation that FTC establish the elimination of quackery as a priority (1), where does this uncertain jurisdiction leave the consumer with regard to harmful "health" services?

Last, we would like to comment on the "1,200-calorie diet," which Dr. Katzin alleged was "based on nutrition proportions recommended by The American Dietetic Association," which was cited without a reference in testimony by David B. Katzin, M.D., Ph.D. The witness list notes that Dr. Katzin was representing the Herbalife Medical/Scientific Advisory Board.

Dr. Katzin's testimony included a chart, "Comparison of Herbalife, Optifast and 1200 Calorie ADA Diet," listing a "1200 Calorie ADA" diet consisting of 10% protein (30 gm), 50% carbohydrate (150 gm), and 40% fat (53 gm). Certainly, we agree with Dr. Katzin that a diet including only 10% protein (30 gm) would be nutritionally inadequate for an individual desiring to lose weight. However, Dr. Katzin does not include an ADA reference among his list of references, nor is this Association able to identify an ADA source recommending these intakes.

In the ADA "Handbook of Clinical Dietetics" (2), a 1,200-calorie diet composed of 65 gm protein, 130 gm carbohydrate, and 50 gm fat is described, along with a sample menu and instructions for dietitians on its use. Since the highest Recommended Dietary Allowance (3) for protein is 56 gm (except for pregnant and lactating women), this diet is more than adequate in protein. ADA does not recommend weight reduction during pregnancy (2).

The American Dietetic Association recommends a calorie-restricted diet as part of an overall program of weight reduction in any person who is overweight as determined by skinfold thickness measurements with calipers and the use of a height-weight table (2). A regular exercise program and behavior modification/diet counseling by a registered dietitian (R.D.) can be effective adjuncts to a weight-reduction diet. R.D.s design weight-loss diets that are nutritionally adequate, tailored to the individual's food habits, consider any underlying disorder (e.g., hypertension), and promote a safe rate of weight loss. ADA recommends a maximum weight loss of 2 lb per week to avoid potential health hazards (4). No drugs are considered to be of value in treating obesity at the present time (2).

Please call on us if you desire technical assistance on this or related issues in the future. In Washington, we are represented by Latham, Watkins & Hills: Contact Cindy Witkin, M.P.H., R.D., at (202) 828-4400. Our Government Affairs office is located at our headquarters in Chicago: Cathy Babington, M.B.A., R.D., Assistant Executive Director, may be reached at (312) 280-5091.

Thank you for this opportunity to present our views.

Sincerely yours,

Julian F. Haynes

Julian F. Haynes, Ph.D.
Executive Director

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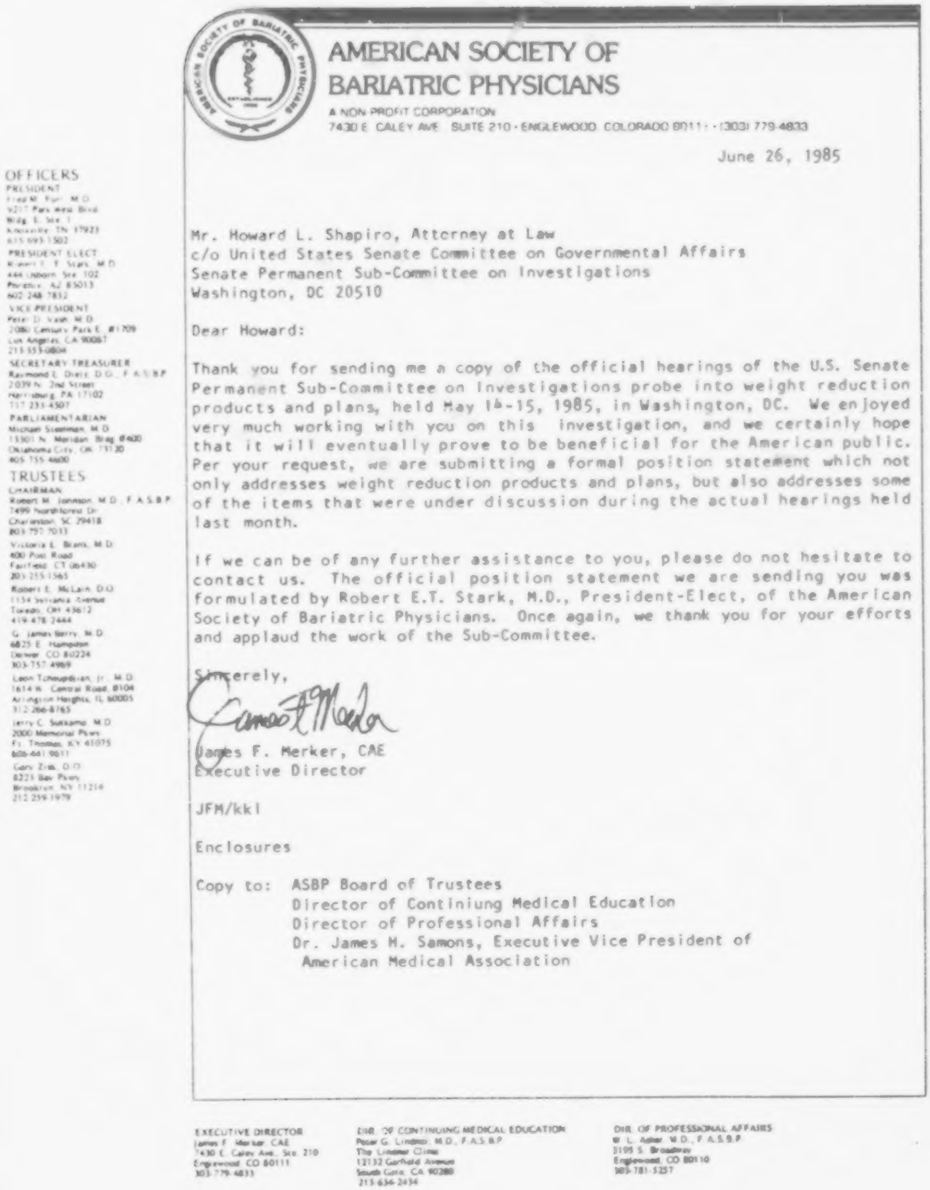
(2) American Dietetic Association: Handbook of Clinical Dietetics. New Haven and London: Yale University Press, 1981.

(3) Food and Nutrition Board: Recommended Dietary Allowances. 9th rev. ed., 1980. Washington: National Academy of Sciences, 1980.

(4) Position Paper on food and nutrition misinformation on selected topics. J Am Diet Assoc 66:277, 1975.



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June 26, 1985

Mr. Howard L. Shapiro, Attorney at Law
c/o United States Senate Committee on Governmental Affairs
Senate Permanent Sub-Committee on Investigations
Washington, DC 20510

Dear Howard:

Thank you for sending me a copy of the official hearings of the U.S. Senate Permanent Sub-Committee on Investigations probe into weight reduction products and plans, held May 14-15, 1985, in Washington, DC. We enjoyed very much working with you on this investigation, and we certainly hope that it will eventually prove to be beneficial for the American public. Per your request, we are submitting a formal position statement which not only addresses weight reduction products and plans, but also addresses some of the items that were under discussion during the actual hearings held last month.

If we can be of any further assistance to you, please do not hesitate to contact us. The official position statement we are sending you was formulated by Robert E.T. Stark, M.D., President-Elect, of the American Society of Bariatric Physicians. Once again, we thank you for your efforts and applaud the work of the Sub-Committee.

Sincerely,

James F. Merker

James F. Merker, CAE
Executive Director

JFM/kkl

Enclosures

Copy to: ASBP Board of Trustees
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AMERICAN SOCIETY OF BARIATRIC PHYSICIANS

Position Statement to the U.S. Senate Permanent Subcommittee on Investigations Hearing on Weight Reduction Products and Plans

The ASBP is the only national medical society that has as its principal professional interest, the treatment of obesity and its associated diseases. The Society is composed of both medical and osteopathic physicians, and it is fully accredited by the Accreditation Council for Continuing Medical Education for its annual national and regional scientific symposiums on obesity.

The ASBP fully endorses the Staff Statement of the Permanent Subcommittee on Investigations, which was made at the onset of the May 14 hearings, especially as that statement relates to Very Low Calorie Diets (V.L.C.). Previous position statements by the ASBP on V.L.C. Diets are enclosed.

These position statements have been unanimously endorsed by our Board of Trustees and by our membership. ASBP was one of the few voices crying in the wilderness when it condemned the "Liquid Protein Diet"--prior to the untimely deaths of many of its victims.

Our position in all V.L.C. Diets is straightforward. Without physician supervision, any and all are fraught with great risk for illness and death. Supervision by "counsellors", the vast majority of whom are simply untrained in any medical or nutritional discipline, would not be tolerated by regulatory agencies in conjunction with any disease entity in the United States, other than obesity. The deliberate use of untrained and ill-informed counsellors is an essential characertisic of both the Cambridge and Herbalife schemes.

Even with physician supervision, V.L.C. Diets represent a serious risk to the obese patient. Some of the women who died as a result of the Liquid Protein fiasco seven to eight years ago, were under physician care while taking the product and before the fatal cardiac arrhythmia occured. Our position is that V.L.C. Diets, if used at all, should be supervised by physicians who have taken the time at medical seminars to learn about the benefits and risks of this treatment modality, as determined by research scientists and physicians who publish their data and results in the scientific and medical literature. The physician's first concern in the treatment of his patient must always be "Non Nocere", i.e., an injunction against harming the patient.

A final cautionary note about the use of V.L.C. Diets, even by knowledgeable physicians, is that these diets have no relationship, whatsoever, to long term results, that is, two to five year results. Any diet with or without benefit of careful research and documentation can result in significant weight reduction--at first; however, only 1% of all dieters 40 pounds or more overweight will successfully reduce 40 pounds and hold that reduction for just one year.

ASBP endorses the statement and testimony of Doctors Judith Stern, F. Xavier, P. Sunyer, and Varro E. Tyler. These experienced and respected researchers and scientists have published in the scientific and medical literature to demonstrate their expertise, regarding the substance of the subcommittee's hearing. We note no corresponding evidence of expertise in the background of Herbalife's physician defender, Dr. David Katzin. There is no evidence of research publication or even membership in any scientific society with a primary interest in obesity therapy or herb use. Dr. Katzin has several outstanding references on page 9 of his statement--including the McGovern Committee report on U.S. Dietary Goals and Doctors Stunkard and Brown. The other scientist referred to by Dr. Katzin is Dr. S. Kreitzman. Dr. Kreitzman was chastised, by the New England Journal of Medicine for his lack of professionalism when he failed to disclose in his article on the safety and effectiveness of Very Low Calorie Formulated Foods, that he was, at the time he wrote the article, a paid consultant for the Cambridge Plan.

ASBP endorses the statements of Mr. Charles Clauson, Chief Postal Inspector, especially with respect to the following:

> "It would seem reasonable to expect that before a seller makes advertising claims for a medical product he would first obtain competent evidence that his claims are valid. As we understand the laws administered by the Food and Drug Administration, before a new drug lawfully can be marketed, the seller must develop objective scientific tests which demonstrate that the drug is safe and will effectively accomplish its claimed purposes. In other words, the seller of a drug is legally obligated to assume the clearly reasonable burden of knowing that his product will do what he claims it will do before offering it to the public.
>
> "A different standard applies with respect to the diet and other medical product schemes which are challenged under our statutes, and, we believe, statutes administered by the Federal Trade Commission. In these cases, the government has the burden of proving that the product will not work as advertised. Typically, the sellers offer little, if any, competent evidence that their product will perform as claimed but, instead, follow a litigation strategy comprised of attempting to find flaws in the government's case and delaying the proceedings in order to prolong their ability to sell the product under challenged advertising claims.
>
> "Legislation might be developed which would shift some of the burden of proving what a product will actually do from the government to the advertiser. Based upon the assumption that a responsible seller should know what his product will do before making claims for it, legislation might be enacted which established a rebuttable presumption that where the government established a prima facie case that a medical product will not perform as advertised, the government is entitled to prevail unless the seller can show that in making the challenged claims he relied upon objective, scientifically valid tests which substantiate his claims."

The ASBP believes that any diet, V.L.C. included, is likely to fail if the emphasis is just on dieting. Every nutritional and medical authority agrees that dieting alone will not work for the long term, unless it is associated with a life long committment to increased physical activity. The obese patient's need for advice on exercise creates an additional burden on the untrained "counsellor" in the Cambridge and Herbalife schemes. These "counsellors" are not only nutritionally unaware, but also ignorant about exercise physiology, especially as it applies to significantly obese individuals.

The ASBP has repeatedly brought to the attention of the FDA and FTC the hazards and risks to the public of unsupervised V.L.C. Diets, as well as the outrageously fraudulent and deceptive advertisements for weight reduction pills, herbs, fibers, etc. We have been very disappointed in the responses of these two agencies to the abuses we have described to them.

By their inability or unwillingness to protect the American public against unproved and untested weight reduction schemes, they have in effect permitted the continued use of untrained and ill-informed lay counsellors in the treatment of significantly at risk obese adults and children. The FDA's regulation, some 6 years after the V.L.C. Liquid Protein deaths, about requiring a warning label for any product which is more than 50% protein, demonstrates the impotence of the FDA in protecting the American public in the realm of obesity quackery and fakery. The more than 50% protein warning, for one thing, makes it appear that over 50% protein is harmful and under 50% is all right. The emphasis of the warning is on the protein quantity when the problem has always been: 1. the extreme paucity of calories in V.L.C. Diets, not the protein content; and, 2. supervision by untrained, ill-informed lay counsellors. All any scheme, not previously in compliance with the 50% rule, had to do was to lower its protein content to below 50% to avoid the warning label requirement. ASBP is convinced that the FDA simply does not have a congressional mandate for protection of the American public in the obesity treatment field.

The 1985 National Institutes of Health Consensus Development Conference on the Health Implications of Obesity has clearly affirmed that obesity is a disease (See Introduction to Final Report). The Final Conference Report also stated that in any circumstance in which excessive weight imposes functional burdens and in disorders which produce those burdens such as heart disease, chronic obstructive pulmonary emphysema, osteoarthritis of the spine, hips or knees, weight reduction in the treatment of these disorders, "should be under the direction of a physician because accurate diagnosis is needed before treatment is started, and weight reduction may have to be accompanied by other treatments. In addition to physicians, the assistance of other health professionals is critical for treatment in any weight-reduction, assessment by a physician of the cardiopulmonary risk of exercise is especially important."

The ASBP trusts and expects that regulatory agencies such as the FTC, FDA, and State Boards of Medical Examiners will take appropriate measures to protect the United States public against charlatans, entrepreneurs, and well meaning, but ill-informed and untrained individuals and groups who desire to participate in the health field. The ASBP trusts and expects that the FDA and FTC will provide protection against untested and unproved theories and entrepreneurial schemes with respect to the disease of obesity, with the same force and vigor that they exert in protecting the American public against abuses in all other recognized diseases.

The final NIH Report in the Health Implications of Obesity outlines the magnitude of the public health problem of obesity as a disease. Once this is appreciated by regulatory agencies such as the FDA, FTC, and State Boards of Medical Examiners, it seems sensible that they will become just as vigilant in protecting the American public against scams, schemes, quackery and fraud in the obesity field as they have in protecting against products in the pharmaceutical field which weren't tested or proved in the United States. Thalidomide and the Cambridge Plan were tested on fewer than 100 individuals in England under strict physician supervision, with no long term follow-up, before it was exported to the United States, where U.S. citizens were used as the experimental group in an untested and unproved pyramid schemes using unlicensed, ill informed and untrained counsellors.

The ASBP notes with interest that many Herbalife clients were willing to testify before the Senate Permanent Subcommittee on Investigations. Had there been a similar Congressional Committee eight years ago on V.L.C. Diets, there would have been thousands of volunteers willing and desirous of testifying on behalf of the Liquid Protein or Last Chance diet--right up to the week that the Liquid Protein dieters started to have fatal cardiac arrhythmias ending tragically in death.

RETS/kkl

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MEMO TO: Howard Shapiro, Attorney at Law
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Senate Permanent Sub-Committee on Investigations

INFORMATION COPIES TO: ASBP Board of Trustees
Director of Continuing Medical Education
Director of Professional Affairs
Dr. James H. Samons, Executive Vice President of
American Medical Association

FROM: James F. Merker, CAE, Executive Director James F. Merker

SUBJECT: ASBP Official Position Statement on Weight Reduction Products and Plans

DATE: July 1, 1985

Reference my letter dated June 26, 1985. On the last page of the Position Statement, which was formulated by Dr. Stark, there was a typing error. The sentence which reads, "Thalidomide and the Cambridge Plan were tested on fewer than 100 individuals in England under strict physician supervision, with no long term follow-up, before it was exported to the United States, where U.S. citizens were used as the experimental group in an untested and unproved pyramid schemes using unlicensed, ill-informed and untrained counsellors." This sentence should read, "The Cambridge Plan was tested on fewer than 100 individuals in England. Under the strict supervision of physicians, there was no long term follow-up, before the Plan was exported to the United States. In this country, U.S. citizens were used as the experimental group in an untested and unproved pyramid scheme using unlicensed, ill-informed and untrained counsellors." Please ensure that this correction is made in the Official Position Statement submitted by this organization.

Thank you for your cooperation and assistance in this matter.

JFM/kkl

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EXHIBIT NO. 1

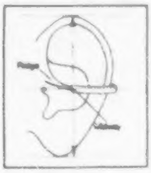
ACU RING™

natural weight control plan

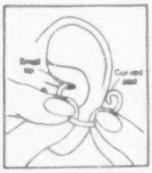
the acu-ring™ plan

Developed by a medical doctor, the Acu-Ring™ Plan is a new concept in weight control. The Acu-Ring™ helps you to focus your attention on what you eat and how much. Unlike drugs, which once ingested are beyond your control, the Acu-Ring™ is there whenever you need it — at those crucial moments when you have to decide whether or not to snack or overeat. With the Acu-Ring™ the control is at your fingertips.

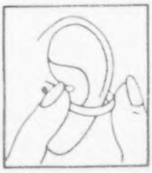
how to use the acu-ring™



Wear the Acu-Ring™ around the ear, placed midway at the end of the ridge as shown in the diagram. Ask a friend to help you place the Acu-Ring™ properly.



Using both hands spread the Acu-Ring™ open and place it around either ear. Place the small tip on the indicated area and the curved pad against the back of the ear.

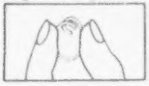


Squeeze the Acu-Ring™ approximately 10 times in succession before meals or whenever you feel the urge to overeat — then decide if you can forego the food... If so, set the food aside until you want it.

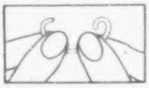
Push the Acu-Ring™ into place when you use it. At other times, the Acu-Ring™ hangs loosely and is kept on the ear for convenience.

adjust the acu-ring™ to fit your ear

If the Acu-Ring™ is too loose it will easily come off and you may lose it; if it is too tight you may feel discomfort. The gap between the small tip and curved pad will determine the fit. Adjust this gap by squeezing or spreading apart the Acu-Ring™ and shape it to fit your ear. The Acu-Ring™ is unbreakable.



FOR A TIGHTER FIT oversqueeze Acu-Ring so that both ends overlap. Let it spring back; a smaller gap will give a tighter fit.



FOR A LOOSER FIT spread apart the Acu-Ring with both hands and let it spring back; a wider gap will give a looser fit.

do's

Do be certain to wear and use your Acu-Ring™ everyday for a full 6 weeks in conjunction with your diet.

Do make it your habit to put on your Acu-Ring™ when you wake up and take it off when you sleep.

Do keep your Acu-Ring™ in its case when not on your ear. It is easy to lose.

Do use the Acu-Ring™ throughout the day, everyday.

Do eat three balanced meals a day, but eat smaller portions.

don't

Don't squeeze your Acu-Ring™ too hard or too often. A light touch is all that's necessary.

Don't sleep with your Acu-Ring™ on, your ear needs sleep too.

Don't use the Acu-Ring™ if your ear becomes irritated.

recommended food program

The essential part of this plan includes a balanced 1200 calorie food program (see back). It is through this reduced caloric intake that you control your weight. The Acu-Ring™ will remind you to follow the diet and help you to eat less.

Persons whose dietary intake is medically monitored (pregnant women, diabetics and others) should only use weight control measures under the direction of their physician.

Daily Intake By Weight	
Carbohydrates	120 grams 4.2 ozs
Protein	70 grams 2.5 ozs
Fat	50 grams 1.8 oz

Select the foods in your diet from the exchange lists. Menus should be planned using the daily menu guide shown below. Foods in the same exchange list are interchangable. For example, when the guide calls for meat exchanges any item in the meat exchange may be used in the amount stated. If two meat exchanges are allowed, double the amount specified or use a single exchange of two foods in the meat exchange list.

Daily Menu Guide	Example
Breakfast	
1 fruit	½ glass orange juice
1 meat	1 egg
1 bread	1 slice toast
1 milk	1 cup milk
1 fat	1 tsp. butter
Lunch	
2 meat	½ cup tuna fish
1½ bread	1 slice bread 3 crackers
1 vegetable	Cucumber
1 fruit	1 apple
Dinner	
3 meat	3 oz. chicken baked
1½ bread	½ corn on cob ¼ cup sweet potato
1 vegetable	½ cup broccoli
1 fat	1 tsp margarine
½ fruit	½ cup fruit cocktail
Bedtime	
1 milk	1 cup skim milk
or	or
1 fruit	½ cup tomato juice
1 bread	6 crackers

Meat Exchange

Beef, pork, lamb, ham, veal, liver	1 ounce	Lobster	1 sm. tail
Chicken, duck, turkey	1 ounce	Salmon or tuna canned	¼ cup
Cold cuts	1 slice	Scallops	1 large
Sardines	3 med	Cheese, American, Chedder, Swiss, Roquefort	1 slice
Clams	5 (small)		
Egg	1	Cheese, cottage	¼ cup
Fish & seafood	1 oz	Peanut butter	1 tbsp

Milk Exchange

Whole milk	½ glass (4 oz.)	Skim	1 glass
Yogurt	½ cup	Butter milk	1 cup

Vegetable Exchange

Any of the following vegetables may be eaten raw in ordinary amounts, but not more than one cup if cooked.

Asparagus
Beans, yellow or green
Bean sprouts
Broccoli
Cabbage
Cauliflower
Celery
Cucumber
Eggplant
Lettuce
Mushrooms
Peppers
Radishes
Sauerkraut
Spinach
Squash, summer
Tomatoes or juice
Turnips
Zucchini
Watercress

½ cup of the following is considered one serving.

Artichokes
Beets
Brussels sprouts
Carrots
Okra
Onions
Pumpkin
Squash, winter

Fruit Exchange

Apple	1	Orange	1
Apple juice	⅓ glass	Orange juice	½ glass
Banana	½	Peaches, fresh	1
Berries	½-1 cup	Peaches, canned	½ cup
Strawberries	¾ cup	Pear, fresh	1
Cherries	15	Papaya	¾ cup
Cantalope	¼ small	Pineapple	½ cup
Fruit cocktail	½ cup	Pineapple juice	⅓ glass
Grapes	15	Plums	2
Grapefruit	½	Prune juice	¼ glass
Mandarine oranges	¾ cup	Raisins	2 tbsp
Mango	½ small	Watermelon	½ slice
Grape juice	¼ cup	Tangerine	1 large

Bread Exchange

Bread	1 slice	Beans, baked, lima, kidney	½ cup
Bagel	½	Corn	⅓ cup
English muffin	½	Corn on the cob	½ ear
Roll	1 small	Peas	½ cup
Pancake	1 (4 inch)	Potato, sweet	¼ cup
Cereals, cooked	½ cup		
dry	¾ cup	Potato, baked	1
Crackers	6	Soup, canned	1 cup
Popcorn	1 cup	Wheat germ	¼ cup
Rice, cooked	½ cup		

Fat Exchange

Butter or margarine	1 tsp	Mayonnaise	1 tsp
Cooking fat	1 tsp	Nuts	6 small
Cream cheese	1 tbsp	Salad oil	1 tsp
Cream		Olives	5 small
Whipped	1 tbsp	Bacon, crisp	1 slice
Half and Half	1 tbsp		

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EXHIBIT NO. 2

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

May 13, 1985

The Honorable William V. Roth, Jr.
Chairman
Senate Permanent Subcommittee
on Investigations
Committee on Governmental Affairs
Washington, D.C. 20510

Dear Chairman Roth:

This is in response to your letter of April 29, 1985, regarding public hearings on weight reduction products and plans that are scheduled for May 14 and 15. Your letter indicated that you were interested in comments from the Bureau of Consumer Protection. Since the receipt of that letter, your staff has indicated orally to staff at the Commission that you would like the Bureau of Consumer Protection's comments in the form of a written statement for the record of the hearing.

The Commission has authorized the Bureau of Consumer Protection to submit the attached statement to assist your Subcommittee in its investigation of weight reduction products and plans. If we may be of further assistance to you or your staff, please do not hesitate to let us know.

Sincerely,

Carol T. Crawford

Carol T. Crawford
Director

PREPARED STATEMENT OF THE

BUREAU OF CONSUMER PROTECTION[*]
FEDERAL TRADE COMMISSION

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS
COMMITTEE ON GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

MAY 14, 1985

WASHINGTON, D.C.

This statement represents the views of the Bureau of Consumer Protection. It does not necessarily represent the views of the Federal Trade Commission or any individual Commissioner.

Introduction

Mr. Chairman and members of the Subcommittee: We are pleased to have the opportunity to discuss the Federal Trade Commission's law enforcement activities regarding deceptive advertising of weight reduction products and plans. The Commission has maintained an active interest in this area for nearly 50 years.[1] The Commission's long-standing concern about deceptive claims or fraudulent products for weight reduction, and our enforcement activities against such products or claims are, however, but one facet of our broader effort to police fraudulent or deceptive food, drug and health care claims. The Commission has always viewed such claims as a particularly important area for Commission enforcement activity because of the significant financial and physical injury that can result, and because those people to whom the claims are directed may be particularly vulnerable to injury from such claims. First, purchasers are injured economically when they pay for cures and remedies that do not work. Second, the bogus cure may itself jeopardize purchasers' health and safety. Third, ineffective remedies may divert purchasers from legitimate medical treatment that could relieve their problems.

This statement describes the Commission's legal authority for prosecuting deceptive or fraudulent claims, and some of our weight reduction product enforcement activities. The statement also describes our liaison with other agencies that have consumer protection enforcement authority. The statement concludes by describing some of the procedural difficulties we encounter in prosecuting deceptive or fraudulent claims.

---

[1] As early as 1937, the Commission issued a cease and desist order against Glenn Laboratories for advertisements for a diet pill called Dr. Thomas' Rx 157, which consisted mainly of desiccated thyroid. In the Matter of Glenn Laboratories, Inc., 25 F.T.C. 302 (1937).

The Commission's Legal Authority

The Commission's authority to proceed against weight reduction claims or frauds derives from Sections 5 and 12 of the Federal Trade Commission Act (the "Act").[2] Section 5 of the FTC Act declares unlawful unfair or deceptive acts and practices in or affecting commerce.[3] Section 12 of the Act specifically prohibits the use of false advertisements regarding food, drugs, cosmetics or devices.[4] The Commission can act under one or both sections to halt certain acts or practices involving deceptive food, drug, or other health care practices.

---

[2] 15 U.S.C. §§ 41 *et seq*. (1982).

[3] 15 U.S.C. § 45 (1982). The Commission evaluates whether a claim is deceptive or unfair according to criteria described in Commission statements defining unfairness and deception. The Commission's definition of unfairness is contained in a 1982 letter from the Commission to Senators Bob Packwood and Robert Kasten, Jr. The criteria were initially articulated in a 1980 letter from the Commission to Senators Wendell H. Ford and John C. Danforth. According to these letters, "unfairness" exists when: (1) consumer injury is substantial; (2) it is not outweighed by countervailing benefits to consumers or competition; (3) it is injury that consumers themselves could not reasonably have avoided. In 1983, after an extensive review of Commission and court decisions, the Commission issued a statement defining deception as a representation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. Letter from James C. Miller III, Chairman, to the Honorable John D. Dingell (Commissioner Bailey dissenting). The Commission also recently issued a policy statement regarding its advertising substantiation doctrine (July 27, 1984). This doctrine requires advertisers to have a reasonable basis to support their claims before they are disseminated. The statement describes how the lack of substantiation may be deceptive, and, among other issues, it addresses the thorny question of how much substantiation is required.

When the Commission believes a violation of Section 5 or 12 has occurred, is occurring or is about to occur, there are a number of civil remedies that it can use to stop the violation and to prevent future violations. For example, the Commission can either seek an administrative cease and desist order, under Section 5 of the Act, or preliminary or permanent injunctive relief in federal court under Section 13 of the Act.[5] Through district court actions, the Commission also can obtain consumer redress.

For violations of existing Commission orders or rules,[6] the Commission is authorized to seek civil penalties. In addition, the Commission has the authority to seek civil penalties in a United States District Court against a company or person the Commission believes has knowingly engaged in an act or practice that was previously found to be unfair or deceptive by the Commission in a litigated final cease and desist order against another respondent.[7] The Commission can seek up to $10,000 per violation per day for such violations. Of course, the Commission also seeks to obtain voluntary compliance when it is appropriate.

---

[4] 15 U.S.C. § 52 (1982).

[5] 15 U.S.C. § 53 (1982).

[6] Where the Commission finds that a deceptive act or practice is prevalent in an industry, it can promulgate what is known as a trade regulation rule (TRR) that has the force of law. Violations of a TRR can subject the violator to penalties of up to $10,000 per violation per day. 15 U.S.C. § 45(m)(1)(A).

Enforcement Activities

As part of our effort to protect the public, the staff continually monitors advertising for unfair or deceptive claims, emphasizing food, drug and health care claims, including weight reduction products or plans, because of their potential for causing serious injury. Further, because ads for some types of products, such as those that can be characterized as "quack" remedies, often do not appear on radio and television networks or in major newspapers and magazines, our efforts include monitoring health magazines catering to individuals who believe in non-traditional treatments and tabloid publications.

The Commission has used its authority to prosecute sellers of fraudulent or deceptive weight reduction products many times over the years. For example, in 1976 the Commission sued Simeon Management Corp. for deceptively advertising a prescription drug used in its weight reduction clinics that was not approved by the

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[7] 15 U.S.C. § 45(m)(1)(B). To meet the statutory requirement for "actual knowledge," which is a condition for recovering civil penalties, the Commission has developed summaries of Commission law that are called "synopses." These synopses, along with copies of relevant Commission decisions are served upon potential respondents. The proof of service is used in a civil penalty action to establish at least a strong presumption of the requisite actual knowledge.

Food and Drug Administration for weight reduction.[8] The Commission used its authority under Section 45(m)(1)(B) to develop a "synopsis" of the decision that could be served on others that appeared to be engaging in the type of practice that was the subject of the Simeon litigation. (A copy of the synopsis is attached as Appendix 1.)

In 1977, the Commission sued Porter & Dietsch for deceptively advertising the X-11 diet pill as a unique product that would allow users of the product to lose weight without restricting normal caloric intake.[9] The final cease and desist order requires the respondents to cease making unsubstantiated claims for its diet products, misrepresenting that the products contain a unique ingredient, and misrepresenting that users of its weight control products can achieve weight loss without restricting their caloric intake.[10] The order also requires the respondents to disclose in their promotional materials that "dieting is required."[11]

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[8] Simeon Management Corp., 87 F.T.C. 1184 (1976), aff'd, 479 F.2d 1137 (7th Cir. 1978).

[9] FTC v. Porter & Dietsch, Inc., et al., 90 F.T.C. 770 (1977), modified, 605 F.2d 294 (7th Cir. 1979), cert denied, 445 U.S. 950 (1980), amendments to order, 95 F.T.C. 806 (1980). A list of the Commission's litigated cases involving weight reduction products, including foods, drugs, devices and cosmetics, is contained in footnote 8 of the Commission's opinion. 90 F.T.C. at 864-65.

[10] 90 F.T.C. at 884-87.

[11] Id. at 886. In addition, the order requires that any diet products containing phenylpropanolamine hydrochloride or similar ingredients with similar properties, or methylcellulose must disclose the following: "Warning: This Product Poses A Serious Health Risk For Some Users. Read the Label Carefully Before Using." Id. at 886.

The Commission has made efficient use of the Porter & Dietsch precedent by using a synopsis to put advertisers, who appear to be engaging in similar practices for the same type of product at issue in Porter & Dietsch, on notice that the Commission has found the practices to be deceptive. (A copy of the synopsis is attached as Appendix 2.) The staff then conducts appropriate follow-up investigations and enforcement actions.[12]

The Commission also has acted against not only drugs but also "devices" deceptively or fraudulently promoted for weight loss. The Acu-Form ear-mold, which was promoted by Acu-Form Weight Control Centers, was touted as a device that would suppress the wearer's appetite. The $300 plastic device was embedded with steel pellets and custom-fitted to the purchaser's ear. According to the promotional material, slight pressure on the steel pellets in the device stimulated acupuncture points in the ear that controlled hunger. Pressure on the points before eating was supposed to result in a physiological suppression of the wearer's appetite, and allow the wearer to lose weight effortlessly. The Commission obtained a consent order against the president of the Acu-Form Weight Control Center, Inc. to settle charges that the claims for the product were unsubstantiated and deceptive.[13]

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[12] A Commission synopsis on baldness cures, for example, that was served on Braswell, Inc. led to the issuance of a complaint against Braswell. This complaint also charged violations of the Commission's mail order rule and misrepresentations of several other products, including one relating to cellulite. The Commission's consent decree settling these charges against Braswell included a judgment for $610,000 in civil penalties. United States v. Braswell, Inc., et al., Civ. Action No. C81-558A (N.D. Ga. 1983).

Liaison Activities With Other Agencies

The Commission's staff consults with other federal agencies, as well as state and local enforcement officials. The Commission's staff maintains particularly close liaisons with the staff at the Food and Drug Administration ("FDA"), and the United States Postal Service, as both these agencies also actively pursue weight reduction and other health frauds. Our contacts with other law enforcement officials, such as State Attorney Generals, can provide valuable information about new fraudulent schemes that may be moving from state-to-state or information about the location of potential respondents or witnesses. Frequently, these contacts help the FTC and the other agencies avoid unnecessary and costly duplication of governmental action. With its extensive in-house medical, nutritional and other health expertise, the FDA also has been able to provide the Commission with valuable technical assistance.[14]

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[13] Thomas A. Dardas, C-3144 (1984).

[14] For example, the FDA recently assisted the Commission in its case against a "hair analysis" laboratory service that deceptively claimed to be able to determine certain important mineral imbalances in the body. FTC v. Furman, 84-0803-A (E.D. Va. 1985).

Procedural and Jurisdictional Problems

Although the Commission has been very successful in combatting health and many other types of deception or fraud,[15] we have encountered some obstacles. The Commission's existing authority is most effective against stable, national firms; its limitations become clear when it is used to prosecute smaller fraudulent operators, who are less likely to stay in one place or in business for very long. Our procedures for obtaining information -- for example, information to determine whether a violation has occurred or the amount or location of a company's assets -- contain impediments that may prevent the staff from obtaining information quickly from an uncooperative company.[16] This is in marked contrast to the streamlined procedures available to agencies such as the Department of Agriculture and the Food and Drug Administration, which are authorized to obtain criminal search warrants in certain programs.

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[15] Examples of recent Commission cases in the health area include: Estee Corp, Docket No. C-3126 (Nov. 16, 1983)(misrepresentations that advertised foods will not elevate the blood sugar level of diabetics); Pharmtech, Docket No. 9163 (May 1984)(misrepresentations that a dehydrated vegetable capsule would reduce the incidence of cancer); P. Leiner Nutritional Products, Docket No. 9172 (1984)(misrepresentations that its wheat germ oil pill improves vigor, stamina, and endurance); and Adria Labs, Docket No. C-3135 (June 1984)(misrepresentations regarding the safety of an over-the-counter analgesic).

Examples of the Commission's actions in non-health area include: FTC v. Internat'l Diamond Corp., Civ. No. 82-0878 (N.D. Cal. 1982)(misrepresentations regarding the investment value of diamonds; over $6.7 million in redress funds secured) (The Commission also has brought seven other investment fraud cases recently and obtained preliminary or permanent injunctions against 71 defendants); FTC v. Rita Walker & Assoc. Inc., Civ. No. 83-29-2962 (D.D.C. Oct. 5, 1983)(involves a scheme allegedly designed to defraud inner-city residents of their homes).

The Commission's primary investigative tool to obtain information about the internal operations of a company is the Civil Investigative Demand ("CID"). Enforcing a CID against a non-cooperative recipient may, however, be a cumbersome and extremely lengthy process. There are no penalties attached to failing to comply with a CID -- the Commission must go to federal court to obtain an enforcement order. Moreover, after we obtain the order, if the recipient still fails to obey it, we must bring a contempt of court proceeding. Consequently, through various procedural maneuvers, firms unwilling to provide information voluntarily and anxious to resist even providing information in response to a process request, can and do avoid responding to a CID for periods of a year or more. This delay makes the CID, as presently constituted, a cumbersome investigative tool in some instances.

Another evidentiary problem with our CID authority is the ambiguity surrounding the Commission's authority to obtain physical evidence. While we believe we have this authority, it is not specifically set out in our statute, as it is under Rule 34 of the Federal Rules of Civil Procedure governing access to documents and other tangible things.

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[16] Where fraud is suspected, the staff may seek to obtain necessary information from third parties rather than the potential respondent. This can avoid tipping off the potential respondent to the Commission's interest, which might lead to the hiding or dissipation of assets that otherwise might be available for consumer redress. This approach, however, is not always feasible or possible.

Other problems we encounter in pursuing companies and individuals engaged in allegedly fraudulent activities -- as opposed to legitimate firms whose practices may occasionally violate the law -- are procedural. For example, to initiate a case in federal court, the complaint must be served on all the defendants. When the Commission sues individual officers or owners of businesses engaged in allegedly fraudulent activities, the Commission may have difficulty serving the complaint if, for example, the intended recipients refuse to answer the door at home, or refuse to let the process server into their office, or if they live outside the jurisdiction in which the company does business. In one recent case, difficulty in effectuating service led the Commission's staff to chase individuals across town and to stake out an airport to serve defendants we believed were going to leave town. It would be preferable if service for federal court actions under the FTC Act were similar to service procedures for serving administrative complaints or orders or other processes of the Commission under that Act.[17] Under the FTC Act, service upon officers or owners of businesses, who are named in their individual capacity in a complaint, may be effectuated by leaving a copy of the complaint at their principal office or place of business.

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[17] 15 U.S.C. § 45(f)(b).

Another procedural problem concerns proper venue of enforcement actions. Presently, under Section 13(b), the Commission can sue defendants only where they reside or transact business. In some instances, defendants do business in a number of jurisdictions through various companies. Although the companies are related, problems may arise as to where to sue to obtain jurisdiction over all the defendants, which may lead to enormous (and costly) procedural battles. This is not a problem under the Magnuson-Moss Warranty Act, which provides that the Court may authorize service of process upon parties who do not transact business or reside in the district where the case is filed if the interest of justice so requires.[18] Unfortunately, that provision does not apply to our Section 13(b) actions against alleged fraudulent operators, potentially forcing the Commission to maintain separate, identical actions against a single interstate fraud.

Another problem that we encounter is that some targets of Commission action try to escape monetary responsibility by seeking refuge in bankruptcy court. Under the Bankruptcy Act, for example, there is an automatic stay of most civil actions. If a debtor files bankruptcy, the Act prohibits a creditor from suing the debtor in another court. The Commission does not believe that the automatic stay provision applies to its law enforcement actions and so far has been successful in arguing that point. Legislative clarification that the Bankruptcy Act's automatic stay provisions do not apply to the Commission's enforcement actions, however, would be helpful.

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[18] 15 U.S.C. § 2310(C)(1) (1982).

Another statutory ambiguity that concerns us relates to the parameters of Section 12 of the FTC Act. As mentioned at the outset, Section 12 prohibits false ads for food, drugs, cosmetics or devices, as defined in Section 15. At present, health services are not expressly included in either section. This may create an anomalous situation in certain cases. For example, while the statute includes devices used in providing the service, it may not include the service itself.[19] While the Commission can always proceed against the deceptive marketing of health care services under Section 5, amending Section 12 to cover "false advertisements" of "health care services" would provide the Commission with an explicit statutory basis for obtaining injunctive relief. It will enable the Commission to provide the District Court with a clear basis on which to enjoin such advertisements, applying the "public interest" standard set out in Section 13(a) of the FTC Act.

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[19] In the hair analysis case referred to in footnote 14 *supra*, for example, it could be argued that the actual providing of the analysis was a "service" that was not covered under Section 12. Of course, the "service" was an act that was covered under Section 5.

Conclusion

This statement has highlighted some of the Commission's enforcement activities regarding weight reduction products. As we mentioned earlier, these activities represent only one facet of the Commission's efforts to combat deception and fraud in the health area. We intend to continue actively pursuing deception and frauds, particularly those aimed at vulnerable groups of people and those that are likely to result in serious financial and physical injury.

APPENDIX 1

SYNOPSIS OF FEDERAL TRADE COMMISSION LAW CONCERNING USE OF PRESCRIPTION DRUGS NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION FOR TREATMENT OF OBESITY OR WEIGHT CONTROL

It is a false, unfair, and deceptive practice in violation of Sections 5 and 12 of the Federal Trade Commission Act to fail to disclose, in any advertisement relating to treatment programs of weight reduction clinics which employ prescription drugs not approved for weight reduction by the Food and Drug Administration, that such treatment programs involve the use of a prescription drug not approved by the FDA for weight reduction purposes. */

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*/ Simeon Management Corp., et al., 87 FTC 1184, 1230-1 (1976) aff'd 579 F.2d 1137 (9th Cir. 1978). The prescription drug at issue in Simeon was human chorionic gonadotropin (HCG).

APPENDIX 2

SYNOPSIS OF FEDERAL TRADE COMMISSION DETERMINATIONS CONCERNING PROMOTION OF PRODUCTS AND PLANS FOR WEIGHT CONTROL*

Porter & Dietsch, Inc.
Docket 9047

This synopsis has been prepared for purposes of 15 U.S.C. §45(m)(1)(B), a law which provides for civil penalties for certain violations of the Federal Trade Commission Act. The Federal Trade Commission has determined that the following acts or practices are deceptive and are unlawful under Section 5(a)(1) of the FTC Act, 15 U.S.C. §45(a)(1).

A. It is deceptive to represent, directly or by implication, that use of an appetite suppressant, and/or methylcellulose, enables a person to lose body weight or fat without dieting or restricting his or her accustomed caloric intake.

B. It is deceptive to represent, directly or by implication, that a weight control product contains a unique ingredient or component, unless the ingredient or component is not present in other available weight control products.

C. It is deceptive to represent, by means of testimonials, directly or by implication, that any particular experience with a weight control product or plan reflects the typical or ordinary experience of users of the product or plan, unless the representation is true.

D. It is deceptive to represent, directly or by implication:

1. that use of a weight control product or plan will result in weight loss or a change in body configuration, without possessing and relying upon a reasonable basis for the representation at the time it is disseminated.

2. that scientific evidence supports a statement about a weight control product or plan, without possessing and relying upon competent scientific evidence that fully supports the statement at the time the representation is disseminated.

Approved: March 1983

Resolution: Approved March 7, 1983 in File 802 3132, Marketers of Weight Control Products and Plans

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* As used here, "weight control" includes the reduction or elimination of fat with or without weight loss. This synopsis is based on the Commission's Porter & Dietsch decision. The decision was approved, with a few changes, by a federal appeals court. A further appeal to the U.S. Supreme Court was turned down. The legal citation for the case is 90 F.T.C. 770 (1977), *modified*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980), *amendments to order*, 95 F.T.C. 806 (1980).

EXHIBIT NO. 4

STATEMENT OF CHARLES R. CLAUSON
CHIEF POSTAL INSPECTOR
BEFORE THE SENATE PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS
MAY 14, 1985

MR. CHAIRMAN:

I AM CHIEF POSTAL INSPECTOR CHARLES R. CLAUSON. I APPRECIATE THE OPPORTUNITY TO APPEAR BEFORE THIS SUBCOMMITTEE TO DISCUSS OUR EFFORTS TO CURTAIL USE OF THE MAILS TO MARKET MISREPRESENTED OR FRAUDULENTLY ADVERTISED WEIGHT REDUCING PLANS, PRODUCTS, AND DEVICES.

THE POSTAL INSPECTION SERVICE IS THE INVESTIGATIVE ARM OF THE UNITED STATES POSTAL SERVICE. IT HAS INVESTIGATIVE RESPONSIBILITY OVER ALL VIOLATIONS OF FEDERAL CRIMINAL LAWS RELATING TO THE POSTAL SERVICE. POSTAL CRIMES FALL WITHIN TWO BROAD CATEGORIES: CRIMINAL ACTS AGAINST THE POSTAL SERVICE OR ITS EMPLOYEES, SUCH AS ARMED ROBBERIES, BURGLARIES OR THEFT OF MAIL, AND CRIMINAL MISUSE OF THE POSTAL SYSTEM SUCH AS THE MAILING OF BOMBS OR OBSCENE MATTER AND, OF COURSE, USE OF THE MAILS TO DEFRAUD THE PUBLIC. THE INSPECTION SERVICE ALSO IS RESPONSIBLE FOR INTERNAL AUDIT OF POSTAL SERVICE OPERATIONS AND FOR THE SECURITY OF POSTAL FACILITIES AND EMPLOYEES. FINALLY, WE ARE RESPONSIBLE FOR INVESTIGATING VIOLATIONS OF A NUMBER OF CIVIL STATUTES RELATING TO THE USE OF THE MAILS INCLUDING THE POSTAL FALSE REPRESENTATIONS STATUTE.

THE NATION'S MAIL SYSTEM HAS BEEN A FAVORITE MARKETING MEDIUM FOR THE SALE OF WORTHLESS OR GROSSLY EXAGGERATED WEIGHT REDUCTION PILLS, POTIONS, AND DEVICES FOR WELL OVER A CENTURY. AS YOU WILL SEE FROM THE CASE SUMMARIES THAT I WILL DISCUSS, MAIL ORDER SALES OF QUESTIONABLE WEIGHT REDUCTION PRODUCTS ENTAIL MULTI-MILLION DOLLAR CONSUMER LOSSES. THE ADVERTISING PITCHES FOR THESE PRODUCTS ARE ALL TOO FAMILIAR. IF ONE LACKS THE WILLPOWER TO CONTROL EATING, A VARIETY OF PILLS ARE OFFERED TO MAKE THE TASK EFFORTLESS. IF ONE'S GENETIC CODE PREORDAINS AN OBESE CONDITION, IT CAN BE CHANGED OVERNIGHT WHILE YOU SLEEP SIMPLY BY FOLLOWING THE PROMOTER'S EASY WEIGHT LOSS METHOD. WHY ENGAGE IN STRENUOUS EXERCISE WHEN A NEW MIRACLE INGREDIENT ACHIEVES THE SAME RESULT WHILE YOU RELAX IN YOUR HOME.

THE COMMON MESSAGE RUNNING THROUGH FALSE ADVERTISEMENTS FOR WEIGHT LOSS PRODUCTS IS ONE OF HOPE. THE CONSUMER IS TOLD THAT THE PRODUCT IS THE RESULT OF RESEARCH CONDUCTED BY THOSE WHO HAVE BEEN ABLE TO TAP A SOURCE OF TRUTH THAT HAS ELUDED THE MEDICAL AND SCIENTIFIC COMMUNITY. MEMBERS OF THE PUBLIC WHO ARE FRUSTRATED BY MEDICAL SCIENCE'S INABILITY TO PROVIDE A COMPLETE, EASY AND INEXPENSIVE SOLUTION TO THEIR WEIGHT PROBLEM ARE OFTEN TOO WILLING TO BELIEVE ADVERTISEMENTS WHICH PROMISE MORE IMMEDIATE, SUCCESSFUL RESULTS.

UNFORTUNATELY, WHERE HOPE IS OFFERED, DISAPPOINTMENT OFTEN IS PROVIDED. MOREOVER, SOME OF THESE PRODUCTS ARE INHERENTLY DANGEROUS OR PRESENT A HEALTH RISK BY ENCOURAGING CUSTOMERS TO RELY UPON INCOMPETENT "SOLUTIONS," INSTEAD OF SEEKING COMPETENT MEDICAL ADVICE.

THE STATUTORY AUTHORITY AVAILABLE TO THE POSTAL SERVICE TO COMBAT THESE SCHEMES INCLUDES TWO OF THE NATION'S OLDEST CONSUMER PROTECTION LAWS: THE CRIMINAL MAIL FRAUD STATUTE, 18 USC §1341 AND THE POSTAL FALSE REPRESENTATION STATUTE, 39 USC §3005.

THE CRIMINAL STATUTE PROVIDES FOR A FINE OF $1,000 AND IMPRISONMENT OF UP TO FIVE YEARS FOR INTENTIONALLY DEVISING A SCHEME TO DEFRAUD AND USING THE MAILS IN FURTHERANCE OF THAT SCHEME. WHILE ITS DETERRENT POWER LIES MAINLY IN THE POSSIBILITY OF A JAIL SENTENCE, WE HAVE OFTEN FOUND THAT COURTS ARE RELUCTANT TO INCARCERATE SO-CALLED "WHITE COLLAR CRIMINALS," PARTICULARLY FOR FIRST OFFENSES. THE $1,000 FINE WOULD SEEM TO HAVE LITTLE DETERRENT EFFECT FOR PERSONS WHO BELIEVE THEIR PROMOTION WILL REAP MUCH MORE SUBSTANTIAL RETURNS.

BECAUSE TARGETS OF CRIMINAL MAIL FRAUD INVESTIGATIONS AND PROSECUTIONS MAY CONTINUE IN BUSINESS DURING THE COURSE OF THE PROCEEDINGS, WE RELY HEAVILY UPON THE FALSE REPRESENTATION STATUTE AND A SUPPORTING INJUNCTION STATUTE (39 USC §3007) TO PROMPTLY PROTECT THE PUBLIC FROM BEING VICTIMIZED. MOREOVER, IT IS OFTEN DIFFICULT TO PROVE INTENT TO DEFRAUD IN DIET OR OTHER MEDICAL CASES BECAUSE THE PROMOTERS TYPICALLY BASE THEIR ADVERTISING UPON PSEUDO-SCIENTIFIC OR UNPROVEN THEORIES WHICH GIVE THE APPEARANCE OF A REASONABLE BASIS FOR THEIR CLAIMS. THE MISREPRESENTATION STATUTE DOES NOT REQUIRE PROOF OF INTENT TO DEFRAUD. RATHER, IT SIMPLY REQUIRES THAT PERSONS OFFERING GOODS OR SERVICES FOR SALE THROUGH THE MAIL REFRAIN FROM MISREPRESENTING THEIR PRODUCTS IN ANY MATERIAL RESPECT.

FALSE REPRESENTATIONS PROCEEDINGS ARE CONDUCTED PURSUANT TO THE ADMINISTRATIVE PROCEDURE ACT (5 USC, CHAPTERS 5 AND 7) AND ARE INITIATED BY THE FILING OF A FORMAL COMPLAINT WITH THE POSTAL SERVICE'S JUDICIAL OFFICER. A COPY OF THE COMPLAINT, NOTICE OF HEARING, AND OUR RULES OF PRACTICE ARE SERVED UPON THE PROMOTER. THE COMPLAINT IS ASSIGNED TO AN IMPARTIAL ADMINISTRATIVE LAW JUDGE, WHO PRESIDES OVER A FORMAL EVIDENTIARY HEARING WHERE THE RESPONDENT MAY BE REPRESENTED BY COUNSEL, PRESENT TESTIMONY, AND CROSS-EXAMINE WITNESSES. AFTER THE HEARING, THE ADMINISTRATIVE LAW JUDGE RENDERS AN INITIAL DECISION EITHER RECOMMENDING OR NOT RECOMMENDING THAT A FALSE REPRESENTATION ORDER BE ISSUED.

THE ENTIRE RECORD, INCLUDING THE TRANSCRIPT OF THE HEARING, IS THEN REVIEWED BY THE JUDICIAL OFFICER. IF THE JUDICIAL OFFICER CONCLUDES THAT THE POSTAL SERVICE HAS PROVEN BY A PREPONDERANCE OF THE EVIDENCE THAT THE STATUTE IS BEING VIOLATED, HE WILL ISSUE A FALSE REPRESENTATION ORDER. A RESPONDENT MAY SEEK JUDICIAL REVIEW OF AN ADVERSE DECISION IN A FEDERAL DISTRICT COURT. WHILE THE FALSE REPRESENTATION CASE IS PENDING, 39 USC §3007 ALLOWS THE FEDERAL COURTS TO ORDER THE POSTAL SERVICE TO DETAIN THE PROMOTER'S INCOMING MAIL UPON A DETERMINATION OF PROBABLE CAUSE TO BELIEVE WE WILL PREVAIL IN THE ADMINISTRATIVE CASE.

THE MAIL ORDER CONSUMER PROTECTION AMENDMENTS OF 1983 (PUBLIC LAW NO. 98-186), HAVE GREATLY ENHANCED THE EFFECTIVENESS OF THE FALSE REPRESENTATION STATUTE. THIS LAW AUTHORIZES POSTAL OFFICIALS TO PURCHASE AND RECEIVE IN PERSON, UPON PAYMENT OF THE ADVERTISED PRICE, PRODUCTS OR SERVICES SOLD THROUGH THE MAIL, THEREBY EXPEDITING THE INVESTIGATION AND LITIGATION OF FALSE REPRESENTATION CASES..

THE 1983 AMENDMENTS ALSO PROVIDE THAT THE FALSE REPRESENTATION ORDER MAY INCLUDE A CEASE AND DESIST ORDER. PREVIOUSLY, THE STATUTE ONLY AUTHORIZED THE ISSUANCE OF A MAIL-STOP ORDER WHICH DIRECTED A POSTMASTER TO RETURN TO SENDERS MAIL RESPONDING TO THE PARTICULAR NAME AND ADDRESS USED IN THE FALSE REPRESENTATION SCHEME. PROMOTERS SUBJECT TO MAIL-STOP ORDERS COULD CIRCUMVENT THIS ORDER BY CHANGING THEIR ADDRESS AND/OR NAME AND CONTINUE TO OPERATE THE SCHEME WITHOUT RISK OF PENALTY. BY AUTHORIZING U.S. DISTRICT COURTS TO IMPOSE A CIVIL PENALTY OF UP TO $10,000 PER DAY AGAINST ANYONE WHO CONTINUES OR

RESUMES A SCHEME WHICH HE OR SHE HAS BEEN ORDERED TO CEASE OPERATING, THE LEGISLATION SHOULD DETER THIS PRACTICE.

WE BELIEVE THIS NEW LAW CONSTITUTES A MAJOR STEP TOWARDS MAKING THE FALSE REPRESENTATION STATUTE A MORE EFFECTIVE TOOL WITH WHICH TO COMBAT MAIL-ORDER MISREPRESENTATION SCHEMES.

FOR MANY YEARS, A MAJOR PORTION OF OUR MISREPRESENTATION CASES HAS INVOLVED DIET PLANS, PILLS AND DEVICES WHICH ALLEGEDLY CAUSE WEIGHT LOSS WITHOUT DIET OR EXERCISE. MANY OF THE WEIGHT LOSS PROMOTIONS WE HAVE CHALLENGED OVER THE YEARS INVOLVE LITTLE MORE THAN NEW ADVERTISING PITCHES FOR LONG-DISPROVED THEORIES. SOME OF THESE ENDURING SWINDLES INCLUDE: GRAPEFRUIT JUICE CONCENTRATES; BULKING AGENTS LIKE CARBOXYMETHYLCELLULOSE AND GUAR; AND APPETITE SUPPRESSANTS LIKE BENZOCAINE AND PHENYLPROPANOLAMINE (PPA). THE LATTER SUBSTANCE, DEVELOPED AS A DECONGESTANT, HAS BEEN TENTATIVELY FOUND BY AN FDA ADVISORY PANEL TO BE AN EFFECTIVE APPETITE SUPPRESSANT WITHIN CERTAIN LIMITS. HOWEVER, THE PANEL'S FINDINGS HAVE NOT YET BEEN ADOPTED BY THAT AGENCY AND, INDEED, GENERATED CONSIDERABLE CONTROVERSY IN THE MEDICAL COMMUNITY. THE MOST COMMONLY CHALLENGED WEIGHT LOSS DEVICES INCLUDE PLASTIC BODY WRAPS WHICH CLAIM TO CAUSE PERMANENT WEIGHT LOSS THROUGH DEHYDRATION CAUSED BY SWEATING IN PARTICULAR AREAS OF THE BODY, AND DEVICES WHICH COMPRESS TISSUE IN PARTICULAR BODY AREAS ALLEGEDLY TO MAKE THE USER SLIMMER. ACCORDING TO OUR MEDICAL EXPERTS, SUCH DEHYDRATION IS MERELY A TEMPORARY WEIGHT LOSS WHICH OCCURS THROUGHOUT THE BODY AND NOT MERELY IN THE AREA WRAPPED IN PLASTIC. SIMILARLY, THE COMPRESSION DEVICES WORK ONLY AS LONG AS THE DEVICE IS WORN. REGRETTABLY, WEIGHT LOSS OCCURS ONLY AS A RESULT OF REDUCING CALORIC CONSUMPTION THROUGH DIETARY CONTROL OR THROUGH INCREASING CALORIC CONSUMPTION THROUGH INCREASING EXERCISE.

I WOULD LIKE TO SUMMARIZE SOME OF THE MORE NOTEWORTHY CASES WE HAVE BROUGHT AGAINST WEIGHT LOSS SCHEMES IN RECENT YEARS IN HOPES THAT THE COMMITTEE MAY DERIVE FROM THIS SAMPLING A FAIR PICTURE OF THE NATURE OF THESE CASES AND THE PROBLEMS WE HAVE ENCOUNTERED.

ONE OF OUR MORE PROMINENT CASES INVOLVED THE "CAMBRIDGE DIET." ADVERTISED AS A RAPID REDUCING FORMULA WHICH WOULD CAUSE WEIGHT LOSS OF SIX POUNDS IN 48 HOURS AND 46 POUNDS IN SIX WEEKS AND "ACTUALLY [REDUCE] FAT AS FAST AS COMPLETE STARVATION, YET ELIMINATES HUNGER," THE ADVERTISING CLAIMS THE PRODUCT WAS COMPLETELY SAFE TO USE AS IT "PROVIDED ALL THE BODY'S RECOMMENDED NEEDS OF VITAMINS AND MINERALS." ALLEGEDLY ENDORSED BY THE MEDICAL COMMUNITY AND BACKED BY HUNDREDS OF SCIENTIFIC AND CLINICAL STUDIES, THE PROMOTERS RECEIVED UP TO 5,000 ORDERS PER DAY AT AN AVERAGE COST OF $9.95 PLUS $2.50 FOR HANDLING AND SHIPPING.

WE ENGAGED THE SERVICES OF A PROFESSIONAL SURVEY RESEARCH FIRM TO ASK PHYSICIANS TO ASSESS THE SAFETY OF THIS DIET. A QUESTIONNAIRE WAS MAILED TO APPROXIMATELY 1,900 PHYSICIANS RANDOMLY SELECTED FROM AN AMERICAN MEDICAL ASSOCIATION MAILING LIST. APPROXIMATELY 80 PERCENT OPPOSED USE OF THE DIET AND CONSIDERED IT UNSAFE. SOME DESCRIBED IT AS A "SEVERELY RESTRICTED CALORIC INTAKE DIET" (I.E., LESS THAN 800 CALORIES PER DAY) SIMILAR TO LIQUID PROTEIN DIETS WHICH WERE REPORTED TO HAVE CAUSED DEATHS. UNDER THE CAMBRIDGE DIET, AN INDIVIDUAL WOULD RECEIVE ONLY 330 CALORIES A DAY. MANY PHYSICIANS RESPONDING TO THE SURVEY STATED THAT NO ONE SHOULD USE THE CAMBRIDGE DIET WITHOUT CAREFUL MONITORING BY A PHYSICIAN AND WARNED THAT CERTAIN INDIVIDUALS SUCH AS CHILDREN, PREGNANT WOMEN, AND THE ELDERLY SHOULD NOT USE IT AT ALL.

IN 1980, BASED UPON OUR INVESTIGATION, WE INITIATED PROCEEDINGS UNDER THE FALSE REPRESENTATION STATUTE AGAINST THE DIET'S PROMOTERS. IN A SUBSEQUENT CONSENT AGREEMENT THE PROMOTERS AGREED THEIR FUTURE ADVERTISING WOULD WARN USERS TO CONSULT THEIR DOCTORS BEFORE STARTING THE DIET AND EMPHASIZE THAT CERTAIN INDIVIDUALS SHOULD NOT USE THE DIET UNDER ANY CIRCUMSTANCES. WE ESTIMATE THAT PRIOR TO THE CONSENT AGREEMENT 125,000 PEOPLE ACROSS THE COUNTRY HAD COLLECTIVELY PAID WELL IN EXCESS OF $1 MILLION FOR THIS DIET.

IN 1982, PRINCIPAL OPERATORS OF THE MARK EDEN COMPANY WERE INDICTED FOR MAIL FRAUD ARISING FROM ALLEGED FALSE AND FRAUDULENT ADVERTISING CLAIMS FOR WEIGHT LOSS DEVICES KNOWN AS THE SAUNA BELT WAIST LINE REDUCER, AN ALLEGED BUST DEVELOPER, AND THREE REDUCING GARMENTS KNOWN AS SLIM SKINS, VACCU-PANTS, AND VACUUM PANTS. SINCE 1979, MILLIONS OF INDIVIDUALS ACROSS THE UNITED STATES PAID AN AVERAGE OF $10 EACH FOR THESE WORTHLESS PRODUCTS. HAD THE DEFENDANT BEEN TRIED AND CONVICTED ON EACH OF THE 13 COUNTS IN THE INDICTMENT, THE MAXIMUM FINE UNDER THE MAIL FRAUD STATUTE WOULD HAVE BEEN $13,000. BUT THROUGH AN INNOVATIVE CIVIL SETTLEMENT NEGOTIATED BY THE UNITED STATES ATTORNEY IN SAN FRANCISCO, THE CRIMINAL INDICTMENT WAS DISMISSED IN RETURN FOR MARK EDEN'S AGREEMENT TO PAY TO THE UNITED STATES THE SUM OF $1.1 MILLION AND TO CEASE FURTHER SALE OF THE PRODUCTS.

BETWEEN JULY 1980 AND SEPTEMBER 1982, 138 FALSE REPRESENTATION COMPLAINTS WERE FILED AGAINST 50 DIFFERENT PRODUCTS MARKETED BY RELATED COMPANIES OWNED AND CONTROLLED BY GLENN BRASWELL. THESE CASES WERE CONCLUDED THROUGH 32 FALSE REPRESENTATION ORDERS AND 15 CONSENT AGREEMENTS. AMONG THE PRODUCTS SOLD BY BRASWELL WERE DIET PILLS, ANTI-AGING PREPARATIONS AND BALDNESS CURES. EVIDENCE IN THIS CASE DISCLOSED THAT THE AMERICAN PUBLIC SPENT MILLIONS FOR BRASWELL'S WORTHLESS PRODUCTS. IN ADDITION, BRASWELL PLED GUILTY TO MAIL FRAUD CHARGES INVOLVING THE FAKING OF BEFORE AND AFTER ADVERTISING PHOTOGRAPHS PURPORTEDLY REVEALING THE DRAMATIC RESULTS OF HIS PRODUCTS, AND WAS SENTENCED TO FIVE YEARS PROBATION. HE WAS ALSO SENTENCED TO A THREE-YEAR PRISON TERM ON FEDERAL INCOME TAX EVASION AND PERJURY CHARGES WHICH DEVELOPED DURING OUR MAIL FRAUD INVESTIGATION.

WE ARE CURRENTLY INVOLVED IN ADMINISTRATIVE LITIGATION UNDER THE FALSE REPRESENTATION STATUTE INVOLVING SEVERAL DIET PRODUCTS IN WHICH THE COMBINED GROSS RECEIPTS OF THE COMPANIES RUN INTO MILLIONS OF DOLLARS. WHERE FINAL DETERMINATIONS HAVE NOT BEEN REACHED IN THESE CASES, IT SHOULD, OF COURSE, NOT BE PRESUMED THAT THE PROMOTERS HAVE VIOLATED THE STATUTE.

A SOUTH FLORIDA PROMOTER OF A VARIETY OF MEDICAL PRODUCTS, INCLUDING SEVERAL DIET PRODUCTS, THE ROBERTSON-TAYLOR CO., WAS THE SUBJECT OF SEVEN CASES IN 1983 AND DREW ENFORCEMENT ATTENTION TO ELEVEN OTHER PRODUCTS IN 1984. IN CONNECTION WITH THE 1984 CASES, FEDERAL JUDGES IN THREE OF THE DISTRICTS WHERE THE PROMOTER RECEIVES MAIL ORDERED DETENTION OF ITS INCOMING MAIL UNDER SECTION 3007 PENDING COMPLETION OF ADMINISTRATIVE FALSE REPRESENTATIONS CASES. PRIOR TO POSTAL SERVICE INTERVENTION, ESTIMATES OF THE COMPANY'S REVENUES WERE NEARLY $1 MILLION PER MONTH. THE PROMOTER HAS DENIED THE POSTAL SERVICE'S CHARGES AND EACH OF THESE CASES REMAINS UNDECIDED AT THE PRESENT TIME.

GENERAL NUTRITION CORPORATION, OPERATING THROUGH RETAIL STORES LOCATED IN MANY CITIES NATIONWIDE, AS WELL AS THROUGH THE MAILS, WAS CHARGED WITH FALSELY ADVERTISING 15 PRODUCTS INCLUDING 9 WEIGHT LOSS PRODUCTS OR DEVICES SOLD THROUGH ITS MAIL ORDER CATALOG. ONE OF THE DIET CASES WAS FULLY LITIGATED AND RESULTED IN A DECISION FAVORABLE TO THE POSTAL SERVICE. THE REMAINING 8 WEIGHT

LOSS PRODUCT CASES WERE SETTLED UNDER AGREEMENTS WHEREBY GNC AGREED TO DISCONTINUE THE CHALLENGED ADVERTISING CLAIMS.

WE HAVE BEEN INVOLVED IN A SERIES OF FALSE REPRESENTATIONS CASES AGAINST WEIGHT LOSS PROMOTIONS OF MR. LEO DABOUB, WHOSE CHAIN OF DIET STORES DOT THE SOUTHERN CALIFORNIA AREA. HIS COMPANIES, NUTRITIONAL RESEARCH, VITA-HEALTH RESEARCH, AMERICAN DIET ASSOCIATION AND HEALTH ENERGETICS CORPORATION, REGULARLY PUBLISH FULL-PAGE ADVERTISEMENTS IN NEWSPAPERS THROUGHOUT THE COUNTRY, OFFERING CONSUMERS DIET PILLS VIA MAIL ORDER. THESE EYE-CATCHING ADVERTISEMENTS, WHICH OFTEN CONTAIN "BEFORE" AND "AFTER" PICTURES OF SUCCESSFUL USERS, TOUT THE PRODUCTS AS MIRACULOUS AND PROMISE READERS FAST AND DRAMATIC WEIGHT REDUCTION. ON THREE SEPARATE OCCASIONS IN 1984 THE POSTAL SERVICE JUDICIAL OFFICER RULED THAT MR. DABOUB'S ADVERTISEMENTS FOR WEIGHT LOSS PRODUCTS VIOLATED HIS CONSENT AGREEMENTS WITH THE POSTAL SERVICE. ORDERS FOR THESE PRODUCTS, WHICH NUMBERED IN THE THOUSANDS, WERE RETURNED TO CONSUMERS. IN ADDITION, MR. DABOUB WAS CHARGED WITH FALSELY ADVERTISING THREE NEW WEIGHT LOSS PRODUCTS. THIS TIME WE SOUGHT A BROAD CEASE AND DESIST ORDER AGAINST MR. DABOUB, REQUIRING HIM TO HAVE COMPETENT AND RELIABLE SCIENTIFIC STUDIES DEMONSTRATING THE EFFECTIVENESS OF ANY WEIGHT LOSS PRODUCT HE MARKETS. FOLLOWING A FULL HEARING, THE ADMINISTRATIVE LAW JUDGE HAS ISSUED AN INITIAL DECISION RECOMMENDING THE ORDER WE SOUGHT AND THE CASE IS PENDING BEFORE THE JUDICIAL OFFICER FOR A FINAL DECISION.

IN 1984, WE FILED AN ACTION UNDER 39 USC §3005 AGAINST ERIC LUCKY LINDER WHO, DOING BUSINESS AS CITRUS INDUSTRIES, PROMOTED NATIONWIDE SUPER GRAPEFRUIT PILLS FOR WEIGHT LOSS. AN EVIDENTIARY HEARING WAS HELD AND THE ADMINISTRATIVE LAW JUDGE RENDERED AN INITIAL DECISION FAVORABLE TO THE POSTAL SERVICE. WE ALSO OBTAINED A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION IN NOVEMBER 1984 WHICH ALLOWED THE POSTAL SERVICE TO DETAIN CITRUS INDUSTRIES' INCOMING MAIL PENDING THE CONCLUSION OF THE ADMINISTRATIVE APPEAL. WE ESTIMATE THAT MR. LINDER WAS RECEIVING $1,000,000 PER MONTH IN THIS MAIL ORDER PROMOTION.

AFTER THE FEDERAL COURT ORDER, MR. LINDER ENTERED INTO A CONSENT AGREEMENT UNDER WHICH THE POSTAL SERVICE RETURNED ALL DETAINED AND INCOMING MAIL TO THE CONSUMER MARKED "PRODUCT NO LONGER AVAILABLE," AND MR. LINDER ALSO AGREED TO THE ISSUANCE OF A CEASE AND DESIST ORDER WHICH PROHIBITS SIMILAR ACTIVITIES IN THE FUTURE.

IN ANOTHER CASE CONCERNING A WEIGHT LOSS PRODUCT CALLED "DREAM AWAY," WHICH IS MASSIVELY ADVERTISED ON LOCAL AND CABLE TELEVISION STATIONS NATIONWIDE, AN ACTION FILED UNDER 39 USC §3005 RESULTED IN AN ADMINISTRATIVE HEARING AND THE CASE IS AWAITING AN INITIAL DECISION.

WORLD COMMUNICATIONS, INC. (WCI) IS THE SUBJECT OF AN ADMINISTRATIVE ACTION IN WHICH WE ALLEGE THAT WCI VIOLATED A PRIOR CONSENT AGREEMENT IN WHICH IT AGREED TO DISCONTINUE CERTAIN ADVERTISING CLAIMS FOR A DIET PILL. THE CURRENT CASE INVOLVES A GRAPEFRUIT CONCENTRATE PILL FOR WHICH, WE ALLEGE, WCI FALSELY CLAIMS WEIGHT LOSS BENEFITS. IN FEBRUARY, THE JUDICIAL OFFICER ISSUED AN INTERIM ORDER, AUTHORIZED BY THE PREVIOUS CONSENT AGREEMENT, AS A RESULT OF WHICH MAIL IN REPLY TO WCI'S ADVERTISING IS BEING DETAINED PENDING A FINAL DECISION IN THE CASE. PRIOR TO THE DETENTION ORDER WE ESTIMATE WCI WAS RECEIVING MORE THAN $540,000 PER WEEK IN RESPONSE TO ITS ADVERTISING.

WE DO NOT HAVE ANY SPECIFIC RECOMMENDATIONS REGARDING LEGISLATION TO CURB THE MAIL ORDER SALE OF FRAUDULENT OR MISLEADING DIET SCHEMES. HOWEVER, IN CONSIDERING THE NEED FOR POSSIBLE LEGISLATION, WE DID DISCUSS A CONCEPT WHICH

MIGHT BE WORTH FURTHER CONSIDERATION. IT WOULD SEEM REASONABLE TO EXPECT THAT BEFORE A SELLER MAKES ADVERTISING CLAIMS FOR A MEDICAL PRODUCT HE WOULD FIRST OBTAIN COMPETENT EVIDENCE THAT HIS CLAIMS ARE VALID. AS WE UNDERSTAND THE LAWS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION, BEFORE A NEW DRUG LAWFULLY CAN BE MARKETED, THE SELLER MUST DEVELOP OBJECTIVE SCIENTIFIC TESTS WHICH DEMONSTRATE THAT THE DRUG IS SAFE AND WILL EFFECTIVELY ACCOMPLISH ITS CLAIMED PURPOSES. IN OTHER WORDS, THE SELLER OF A DRUG IS LEGALLY OBLIGATED TO ASSUME THE CLEARLY REASONABLE BURDEN OF KNOWING THAT HIS PRODUCT WILL DO WHAT HE CLAIMS IT WILL DO BEFORE OFFERING IT TO THE PUBLIC.

A DIFFERENT STANDARD APPLIES WITH RESPECT TO THE DIET AND OTHER MEDICAL PRODUCT SCHEMES WHICH ARE CHALLENGED UNDER OUR STATUTES AND, WE BELIEVE, STATUTES ADMINISTERED BY THE FEDERAL TRADE COMMISSION. IN THESE CASES, THE GOVERNMENT HAS THE BURDEN OF PROVING THAT THE PRODUCT WILL NOT WORK AS ADVERTISED. TYPICALLY, THE SELLERS OFFER LITTLE, IF ANY, COMPETENT EVIDENCE THAT THEIR PRODUCT WILL PERFORM AS CLAIMED BUT, INSTEAD, FOLLOW A LITIGATION STRATEGY COMPRISED OF ATTEMPTING TO FIND FLAWS IN THE GOVERNMENT'S CASE AND DELAYING THE PROCEEDINGS IN ORDER TO PROLONG THEIR ABILITY TO SELL THE PRODUCT UNDER CHALLENGED ADVERTISING CLAIMS.

LEGISLATION MIGHT BE DEVELOPED WHICH WOULD SHIFT SOME OF THE BURDEN OF PROVING WHAT A PRODUCT WILL ACTUALLY DO FROM THE GOVERNMENT TO THE ADVERTISER. BASED UPON THE ASSUMPTION THAT A RESPONSIBLE SELLER SHOULD KNOW WHAT HIS PRODUCT WILL DO BEFORE MAKING CLAIMS FOR IT, LEGISLATION MIGHT BE ENACTED WHICH ESTABLISHES A REBUTTABLE PRESUMPTION THAT WHERE THE GOVERNMENT ESTABLISHED A PRIMA FACIE CASE THAT A MEDICAL PRODUCT WILL NOT PERFORM AS ADVERTISED, THE GOVERNMENT IS ENTITLED TO PREVAIL UNLESS THE SELLER CAN SHOW THAT IN MAKING THE CHALLENGED CLAIMS HE RELIED UPON OBJECTIVE, SCIENTIFICALLY VALID TESTS WHICH SUBSTANTIATE HIS CLAIMS.

THANK YOU FOR THE OPPORTUNITY TO APPEAR BEFORE THIS SUBCOMMITTEE. I WOULD BE HAPPY TO ANSWER ANY QUESTIONS.

EXHIBIT NO. 7

My name is Sue Rohrke. I am 47 years of age, in good health, and employed by the State of California as a Tax Compliance Representative III (Supervisor) with the Department of Health Services. I bought the Herbalife Product in August 1984.

I used the Protein Powder twice per day with low-fat milk. I took the Formulas 2, 3, and 4, as directed, three times per day. I ate a light meal at night. I did this for 30 days.

At the end of 30 days, I was on vacation in San Diego with my husband when I collapsed three times in one day. The third time I collapsed, I was rushed, by ambulance, to Mercy Hospital in San Diego, where a "blood panel" test was performed.

Dr. Andrew Israel, the Emergency Room physician, came to where I was and asked me if I had been taking any diuretics lately. I said I had been taking Herbalife. He said that it had stripped me of my potassium.

I remained in the hospital for several hours while an intravenous feeding was administered and hospital staff had me drink liquid potassium. The hospital released me with more potassium to drink that evening.

As a result of collapsing, I have an injured ankle that will never completely heal.

My husband has a very real fear from seeing me collapse. He thought I had died the first time I collapsed.

I feel strongly that Herbalife almost killed me!

As an aside, Herbalife is now dissolving the Herbalife Inc. company. I am assuming that the company will continue to sell their product under another name. Why?

I am now in the process of suing Herbalife Inc.

Signature

May 9 1985
Date

STATEMENT
OF
BERNARD LEHMAN

My name is Bernard Lehman. I currently reside in Anaheim, California, with my wife Debra and three daughters. I have prepared this statement to explain my recent experiences with Herbalife International.

These experiences began this past winter, when we were living in Antioch, Tennessee, which is outside Nashville. I have previously worked in the country western music business, among other businesses, but I have not been able to work for a while because I have ~~leukemia~~ HODGKIN'S LYMPHOMA BL. I was in poorer condition than I am now when I was still in Nashville and I was basically bedridden.

Phil and Sandy Jones were neighbors of ours in Nashville, and Sandy Jones worked as a waitress in a local Shoney's BL restaurant. Gideon Paul Mena, an Herbalife distributor, had basically set up offices at tables at two Shoney's BL restaurants, including the one where Sandy Jones worked.

On January 12, Mena came to our house with Sandy and he gave us his best Herbalife sales pitch for hours and hours ON DIFFERENT DAYS BL. He explained that Debra could lose weight taking Herbalife products, which she wanted to do. He also told us how we, particularly Debra, could make lots of money by becoming an Herbalife distributor, and we definitely needed some money. And Mena said that the Herbalife products would help to cure my cancer. He told us this orally and showed us some brochures which said this. However, he gave us different brochures without this information and said that he only had one copy of the special brochure, and he had to keep it for his use. Mena basically said that the Herbalife products would act as a cure-all.

We wanted to believe in everything Mena told us and we definitely needed money. We also wanted to try the products before we sold them, and I had a relative [illegible] friends in the Houston area who had used Herbalife and thought it was great. We bought [illegible] ~~several~~ distributor kit~~s~~ [illegible] complete kits for $95.14, and sold one kit to Sandy Jones. By buying several kits we were able to get a 25% discount. A copy of our distributorship application is attached.

When we tried the products we both had bad reactions. I used Formulas 1-4 and Schizandra Plus, which supposedly had the anti-cancer ingredients, and something else (I can't remember which product) for three or four weeks. Mena also told us that the Schizandra Plus would help my lungs and increase my breathing capacity. I was trying to gain weight at this time but was unable to do so. It was very difficult for me to gain weight because my illness often took away my appetite. But I also had nausea and dizziness and a fever when I took the products. And there was no improvement in my cancer.

Debra took Formulas 1-4 just as they instructed, having one small meal per day. She also took the Herbal Aloe Juice and the NRG pills, but these pills made her very nervous and hyper. Mena told her to cut down from 2 pills to 1 but this didn't help. Debra stayed on the Herbalife for about 2 weeks. She only lost 2 pounds and she also had nausea. She also had extreme stomach pains and went to a doctor who told her to stop taking the Herbalife right away. The stomach pains have continued in California, and she has been to a doctor here. I also learned that a daughter of mine from a previous marriage had been GIVEN SOME DL buying Herbalife from our friends in Houston. She is extremely obese. FROM AN INACTIVE THYROID DL I found out that the Herbalife products made her very ill.

Nevertheless, Mena wanted to sell us more Herbalife products and he would call us all the time. He would come to our house and shovel the snow on the pathway so he could get in. As my wife says, we got suckered, because we believed that we could make lots of money and we thought our own bad reactions to taking the products was unusual.

Mena explained that by buying lots of products right away, ~~we~~ MY WIFE DL could instantly become an Herbalife "Supervisor" and get larger discounts. So ~~we~~ SHE DL bought $1762 worth of products with a certified check on Juanuary JANUARY DL 28, which included 3 cases each of the most popular items. This is an extremely large amount of money for us, but we were able to get a 42% discount on the products. We also spent about another $23 for 1000 Herbalife flyers. Our receipt for the product purchases is attached.

Debra and I tried to sell Herbalife but we got nowhere. She distributed flyers and I made phone calls. TRYING TO HELP HER DL We kept asking Mena for advice and assistance but he didn't help us at all. What we found was that anybody around Nashville who was interested was already a distributor. No one wanted to buy it.

Debra made three sales total. One sale was to a friend who also got sick right away.

By this time we wanted to get our money back from Mena, but he refused, and he became real hard to contact. Finally, Mena came over and said he only had $1000 with him so that was all he could buy back at that time. He refused to take back Kindermins, Tang Kuei, Lifeline, and K-8 because he said they didn't sell at all. So he left us with these and some of the weight loss products, about $700 worth. We still have all of this, because after this meeting Mena vanished. He had an answering machine take his calls and never would call back. Debra told me that even though he only had $1000 with him, she saw one or two large personal checks which Mena had which he claimed came from customers. One was for $25,000 and Debra saw this check and tried to locate the woman who wrote the check to find out if she was really a customer but she couldn't find her.

We moved to California recently and stayed with relatives at first. We are now moving into our own house in Anaheim. The doctors here have helped me a lot and the climate is much better for me but we still don't know if my cancer is in remission, and the overall prognosis remains poor.

On March 19, I called the Herbalife public relations department in Los Angeles. I was on hold for a while and then got to speak to Al Levine. I explained what had happened to us. He told me that distributors are not entitled to refunds and finally he told me to "stick it up my ass" and that's a direct quote which I wrote down. He also said that he would make a note of Mena's cancer claims. This conversation lasted 13 minutes and cost me $5.11, according to my phone bill.

I feel that my wife and I were taken advantage of by Herbalife and I am very bitter. We cannot afford to to absorb a $700 loss. I am on Social Security and can't work and our income is limited. I would just like to get rid of the Herbalife products we still have and forget about them. I hope that our story prevents others from the same problem.

Date: MAY 9, 1985

Bernard Lehman

Bernard Lehman
Anaheim, California

APPLICATION FOR DISTRIBUTORSHIP

HERBALIFE

HERBALIFE INTERNATIONAL
9800 La Cienega Boulevard
P.O. Box 80210
Los Angeles, California 90009

FOR OFFICE USE ONLY 1379347

APPLICANT INFORMATION

LAST NAME ☐☐☐ FIRST ☐☐☐ MIDDLE INITIAL ☐

SOCIAL SECURITY NUMBER ☐☐☐ ☐☐ ☐☐☐☐

STREET ADDRESS

CITY

STATE

ZIP CODE

AREA CODE TELEPHONE NUMBER

DATE OF BIRTH

COUNTRY OF PERMANENT LEGAL RESIDENCE ADDRESS, IF DIFFERENT FROM ABOVE

Name applicant and all your up-line Sponsors between you and your 1st up-line Supervisor.

Applicant Debra [illegible] Lehman
SS# [illegible] 5[illegible] 2[illegible]15

1st Sponsor G. P. Mena
SS# 306 44 7954

2nd Sponsor
SS# ☐☐☐ ☐☐ ☐☐☐☐

3rd Sponsor
SS# ☐☐☐ ☐☐ ☐☐☐☐

4th Sponsor
SS# ☐☐☐ ☐☐ ☐☐☐☐

5th Sponsor
SS# ☐☐☐ ☐☐ ☐☐☐☐

6th Sponsor
SS# ☐☐☐ ☐☐ ☐☐☐☐

1st Supervisor G. P. Mena
SS# 306 44 7954

SPONSOR INFORMATION

SPONSOR'S NAME: Gideon Paul Mena
STREET ADDRESS: PO Box 110397
CITY STATE ZIP: Nashville TN 37211
SPONSOR'S SOCIAL SECURITY #: 306 44 7954
SPONSOR'S TELEPHONE NUMBER: (615) 331-5421

SUPERVISOR'S NAME: Gideon Paul Mena
STREET ADDRESS: P.O. Box 110397
CITY STATE ZIP: Nashville, TN 37211
SUPERVISOR'S SOCIAL SECURITY #: 306 44 7954
SUPERVISOR'S TELEPHONE NUMBER: (615) 331-5421

AGREEMENT OF DISTRIBUTORSHIP

Upon acceptance of this Application by HERBALIFE, the undersigned applicant for a distributorship (hereinafter called Distributor) agrees:

1. Distributor will operate his (her) own business, will buy Herbalife products for cash, will promote their sale and will abide by all Herbalife policies and rules, as issued from time to time, including policies set forth in the Herbalife Career Book and other Herbalife publications.
2. Distributor is an independent contractor (for Federal tax purposes, and otherwise), and is not an employee, legal representative or agent of Herbalife or of any Herbalife distributor.
3. Herbalife, insofar as it is reasonably possible, will sell for cash to Distributor Herbalife products in whatever quantity Distributor may require.
4. For a period of three (3) years after termination of this agreement Distributor will hold in confidence any trade secrets, formulas, sales and distribution systems, business information, and literature which Distributor acquired during the term of this agreement and will not use directly or indirectly such items. For such period Distributor also agrees not to enter or participate in a competing business or business activity.
5. If Distributor fails to comply with the terms of this agreement, Herbalife may revoke the Distributorship.
6. Without the written consent of Herbalife this Distributorship may not be assigned.
7. I understand that the signing of this agreement and my purchase of a distributor kit is all that is needed to become a distributor. If within 90 days I decide not to continue as a distributor, I shall submit my written, notarized resignation to Herbalife; I will then return the kit to my original sponsor, who will give me a pro rata refund, i.e., a refund only for those unused kit contents that are still in good and resalable condition.
8. This agreement is binding upon and inures to the benefit of the parties, their heirs and successors in interest. If any provision of this Agreement is found to be unenforceable or invalid, the validity of the remaining provisions shall not be affected.

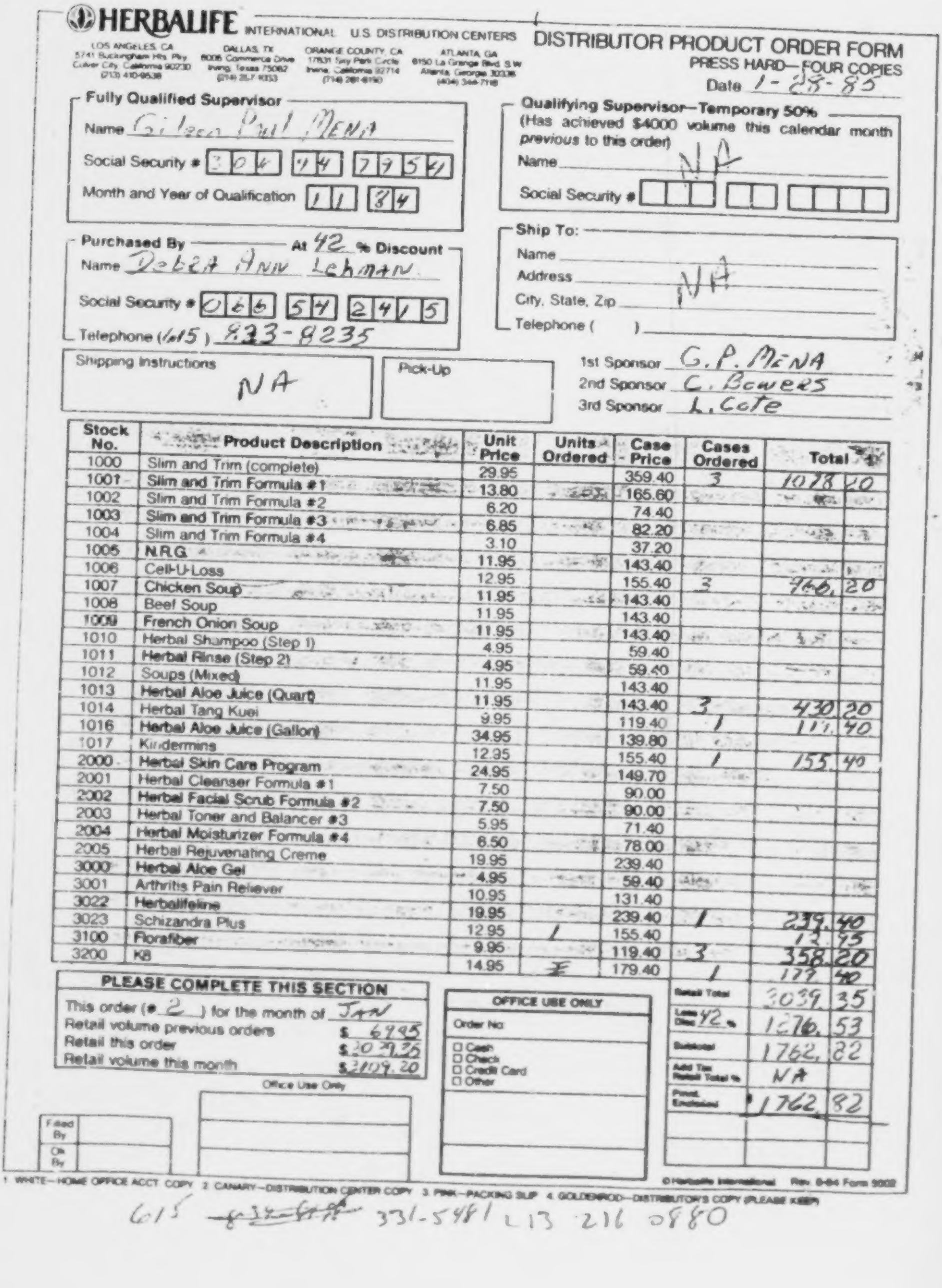
Dated at ____ (City, State, Country) on ____, 198__

Applicant's Signature

Application Accepted for Herbalife International
By: Mark Hughes

Spouse's Signature (If a co-distributor)
Spouse's SS# (If a co-distributor) ☐☐☐ ☐☐ ☐☐☐☐

1. WHITE — HOME OFFICE COPY 2. PINK — SPONSOR'S COPY 3. CANARY — SUPERVISOR'S COPY 4. GOLDENROD — APPLICANT'S COPY 4010 Rev. 9/84



HERBALIFE INTERNATIONAL U.S. DISTRIBUTION CENTERS

LOS ANGELES, CA
5741 Buckingham Hts. Pky
Culver City, California 90230
(213) 410-9538

DALLAS, TX
8005 Commerce Drive
Irving, Texas 75062
(214) 257-9353

ORANGE COUNTY, CA
17531 Sky Park Circle
Irvine, California 92714
(714) 261-6150

ATLANTA, GA
6150 La Grange Blvd. S.W.
Atlanta, Georgia 30336
(404) 344-7118

DISTRIBUTOR PRODUCT ORDER FORM

PRESS HARD—FOUR COPIES

Date 1-28-85

Fully Qualified Supervisor
Name Gilzen Paul MENA
Social Security # 304 44 7754
Month and Year of Qualification 11 84

Qualifying Supervisor—Temporary 50%
(Has achieved $4000 volume this calendar month *previous* to this order)
Name NA
Social Security #

Purchased By At 42 % Discount
Name DebRA ANN Lehman
Social Security # 066 54 2415
Telephone (615) 833-8235

Ship To:
Name
Address NA
City, State, Zip
Telephone ( )

Shipping Instructions NA

Pick-Up

1st Sponsor G.P. MENA
2nd Sponsor C. Bowers
3rd Sponsor L. Cote

Stock No.	Product Description	Unit Price	Units Ordered	Case Price	Cases Ordered	Total	
1000	Slim and Trim (complete)	29.95		359.40	3	1078	20
1001	Slim and Trim Formula #1	13.80		165.60			
1002	Slim and Trim Formula #2	6.20		74.40			
1003	Slim and Trim Formula #3	6.85		82.20			
1004	Slim and Trim Formula #4	3.10		37.20			
1005	N.R.G.	11.95		143.40			
1006	Cell-U-Loss	12.95		155.40	3	466.	20
1007	Chicken Soup	11.95		143.40			
1008	Beef Soup	11.95		143.40			
1009	French Onion Soup	11.95		143.40			
1010	Herbal Shampoo (Step 1)	4.95		59.40			
1011	Herbal Rinse (Step 2)	4.95		59.40			
1012	Soups (Mixed)	11.95		143.40			
1013	Herbal Aloe Juice (Quart)	11.95		143.40	3	430	20
1014	Herbal Tang Kuei	9.95		119.40	1	119.	40
1016	Herbal Aloe Juice (Gallon)	34.95		139.80			
1017	Kindermins	12.95		155.40	1	155.	40
2000	Herbal Skin Care Program	24.95		149.70			
2001	Herbal Cleanser Formula #1	7.50		90.00			
2002	Herbal Facial Scrub Formula #2	7.50		90.00			
2003	Herbal Toner and Balancer #3	5.95		71.40			
2004	Herbal Moisturizer Formula #4	6.50		78.00			
2005	Herbal Rejuvenating Creme	19.95		239.40			
3000	Herbal Aloe Gel	4.95		59.40			
3001	Arthritis Pain Reliever	10.95		131.40			
3022	Herbalifeline	19.95		239.40	1	239.	40
3023	Schizandra Plus	12.95	1	155.40		12.	95
3100	Florafiber	9.95		119.40	3	358.	20
3200	K8	14.95		179.40	1	179.	40

PLEASE COMPLETE THIS SECTION

This order (# 2) for the month of JAN
Retail volume previous orders $ 69.85
Retail this order $ 3039.35
Retail volume this month $ 3109.20

Office Use Only

Filed By
Ok By

OFFICE USE ONLY

Order No.
☐ Cash
☐ Check
☐ Credit Card
☐ Other

Retail Total	3039.	35
Less Disc. 42 %	1276.	53
Subtotal	1762.	82
Add Tax Retail Total %	NA	
Final Enclosed	$1762.	82

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1. WHITE—HOME OFFICE ACCT. COPY 2. CANARY—DISTRIBUTION CENTER COPY 3. PINK—PACKING SLIP 4. GOLDENROD—DISTRIBUTOR'S COPY (PLEASE KEEP)

615 ~~[illegible]~~ 331-5481 213 216 0880

ACCOUNT F3958849 INVOICE 43290698 CYCLE 18 APRIL 13, 1985 3 134188

DETAIL OF MCI SERVICE CALLS

DATE	TIME	RT	NO. CALLED	MIN	$ AMT	DATE	TIME	RT	NO. CALLED	MIN	$ AMT
[redacted]				[redacted]	[redacted]	[redacted]					
MAR 19	11:37A	D	404-344-7118	2	.71	- HERBALIFE - ATLANTA - WAREHOUSE					
MAR 19	11:41A	D	213-216-0880	13	5.11	- HERBALIFE - AL LEVINE					
[redacted]				[redacted]	[redacted]						

MCI SERVICE CALLS $24.53

D = DAY E = EVENING N = NIGHT/WEEKEND

the nation's long distance phone company

EXHIBIT NO. 9

STATEMENT
OF
CYNTHIA GUILLAUME LEE

My name is Cynthia Guillaume Lee. I am 35 years old and I work for Martin Marietta Aerospace as a Sr. Financial Specialist.

My husband's name is Bivian Lewis Lee, Jr.. If he were alive today, he would be 36. He was a former NFL player. He played professional football until 1976 when he decided to retire. He later became a salesman.

We were married in 1974, and have 2 children, Tamica Marnie Lee, 5 years old and Bivian Lewis Lee, III, 3 years old. We lived in Denver for a number of years ~~but~~ [illegible] in 1976 returned to New Orleans in 1983.

Bivian was in excellent health. After retiring from football in 1976 he continued to be active. He played in a softball league. He exercised daily, was very active with the children and was very much a family man. He ate well and outside of minor colds he was never sick.

Late in October of 1984 Bivian came home from work and told me he met a former NFL player who was selling Herbalife outside of his regular job and was doing very well. He said that you could make an extra $3,000 to $4,000 a month. Then he explained to me about the Pyramid. Well the extra money sounded real good to Bivian so he decided to become a distributor. He also decided to try it out himself which was shocking to me. Bivian was very much against taking any kind of diet product and he wasn't overweight. When I asked him why he was taking it, he said that if was going to sell it he would at least try it out. Well the next day he came home with Herbalife (one large can of powder mix and 3 bottles of vitamins). He started taking the Herbalife the next day. At first, he continued exercising, and ate one regular meal in the evening. At the beginning of the following week he kept telling me he was hyper, but he continued to talk positively of Herbalife.

After a few days, however, he began to complain. For almost two weeks he complained about shortness of breath; he began vomiting after his meals, having diarrhea, and getting chills. When I told him I was worried about him, he said that according to the Herbalife pamphlet it was a normal symptom. "It's just cleaning my system out," he said. By the end of the second week on Herbalife he had lost all of his appetite.

Bivian felt so bad he couldn't work. He came home complaining how bad he felt and how he hadn't been himself ever since he took Herbalife. He threw all the products out.

On the Friday before he died, we had a small family gathering celebrate little Bivian's third birthday. Bivian was feeling very bad and did not look well. He didn't eat anything; he just drank water. My family observed how bad he looked. He commented to them that ever since he had taken Herbalife he has not been the same. My mother recommended a doctor. He said he would go see one on Monday, November 12, if he wasn't any better over the week-end. Later that night, about 1 a.m. I was awakened by a loud sound. I ran to the kitchen and he was stretched out on the floor. I yelled, he opened his eyes, and asked me to help him get up. He had bruised his face on the floor, cut his lip, and bruised his leg. He wanted fresh air so

I helped him walk outside. He said that he was weak from not eating, and he was getting up to come to bed when he blacked out. We were both at this point very alarmed and agreed that he would get to a doctor the first thing in the morning.

He didn't sleep at all that night. The next morning, Saturday, we had trouble finding a doctor, but eventually made an appointment for 10 o'clock on Monday, November 12, 1984. We never made it to the doctor.

On Saturday, Bivian was able to eat a little soup and crackers and drink water. He felt terrible, his stomach was swollen. His symptoms persisted. On Sunday he ate a little soup and crackers again and drank water. Later, about 3 a.m. (Monday morning) he awoke me, and asked me to fix him something to eat. I fixed him some food, but had to feed him in bed because he was very weak. He ate some of the food. He wanted fresh air, so I walked him outside. It was cold so I went inside to get his robe and brought it to him. I went to get my robe and as I proceeded to go outside he was coming in bent over and breathing very fast. I told him I was going to call the Paramedics and as I was leaving the room I turned around and he was standing straight up, arms straight out, with his back facing me. I grabbed his arm. It was rigid. He then fell, I raced to the phone and called the Paramedics. They came right away and immediately began working on him, constantly asking me questions. They took him to the hospital where they pronounced him dead.

I know that I'm not a doctor. I know that I'm not qualified to give medical opinions. But I do know that my husband was a perfectly healthy man. I saw him deteriorate from the perfectly healthy man to his death. And it all began when he started taking Herbalife.

I want to tell what happened to me--it's not easy for me to do this--because, I want this Subcommittee, or the Federal Food and Drug Administration or somebody to investigate why my husband was alive and well until he started on the Herbalife products and now he's dead. I want to encourage the Subcommittee to look into this so that other young mothers won't find themselves in my position.

DATE: May 14, 1985

Mrs Cynthia Lee

Mrs. Cynthia Lee
New Orleans, LA

AFFIDAVIT

I, Theodore B. Van Itallie, do solemnly swear as follows:

1. I am a physician, licensed to practice medicine in New York and Massachusetts. I was graduated from Harvard University in 1941 and received my medical degree from Columbia University in 1945.

2. I am a Diplomate, certified by the American Board of Internal Medicine and the American Board of Nutrition since 1954.

3. I am currently a Professor of Medicine at the College of Physicians and Surgeons, Columbia University in New York. I am also Director of the Obesity Research Center, St. Luke's-Roosevelt Hospital Center in New York, a position I have held since 1974.

4. I have served as President of the American Society of Clinical Nutrition.

5. I have been a member of the Food and Nutrition Board of the National Research Council.

6. I have served as Editor-In-Chief of the American Journal of Clinical Nutrition.

7. I have served as Special Advisor on Human Nutrition to the U.S. Surgeon General.

8. I am currently a member of a number of professional organizations, including the American Society of Clinical Investigation, the American Institute of Nutrition, the Society for Experimental Biology and Medicine, the American Society of Clinical Nutrition.

8. As part of my research, I have reviewed the Report prepared under contract with the Food and Drug Administration by the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology. That report reviewed all available information on the 1977-1978 deaths of 17 obese but otherwise healthy people who were using liquid protein diets. I have also reviewed other literature on the deaths, including: "Sudden Unexpected Death in Avid Dieters Using the Liquid-Protein-Modified-Fast-Diet: Observation in 17 Patients and the Role of the Prolonged Q-T Interval", by J.M. Isner, H.S. Sours, et. al.

9. I co-authored an article, entitled "Cardiac Dysfunction in Obese Dieters: A Potentially Lethal Complication of Rapid, Massive Weight Loss," that was published in May of 1984 in the American Journal of Clinical Nutrition. The article discusses the 17 obese but otherwise healthy people on very low calorie diets who died of cardiac arrythmia. It explains my thesis that the cardiac dysfunction is related to protein depletion involving the heart. Basically, severe restriction of caloric intake causes the body to utilize and deplete its protein. The heart is a muscle, made of protein, and it is not spared.

The information available makes a convincing case that the depletion of protein from the heart may be followed by cardiac arrythmia and death. I refer to this as the "liquid protein syndrome", but it may develop from any drastic reduction in caloric intake.

My thesis further holds that persons with lesser stores of body fat are more likely to experience the cardiac dysfunction. Fatter dieters seem to survive longer because they are better able to conserve their body protein.

10. I have reviewed the following information about Margaret Dunn:
    a) the report of Death, prepared by the Office of the Medical Investigator for the State of New Mexico, dated February 12, 1985;
    b) the Autopsy Report, dated March 26, 1985; and
    c) the Toxicological Report, dated February 25, 1985.

    I have also been provided the following factual summary: Mrs. Dunn was a healthy, 20-year-old woman who delivered a baby on October 20, 1984. At that time she weighed 158 pounds. She started an Herbalife diet about November 1, 1984. Her doctor examined her on November 7 and 28, 1984 and January 11, 1985. The doctor found her well and weighing first 141, then 137, then 130. On February 12, 1985, Margaret Dunn died of a probable cardiac arrythmia; she weighed 122 pounds.

11. Based on the information provided, Margaret Dunn's death is consistent with the "liquid protein syndrome."

12. I have reviewed the following information about Bivian Lee:
    (a) the Autopsy Protocol prepared by the Orleans Parish Coroner's Office, dated November 12, 1984;
    (b) the Forensic Laboratory Report dated November 26, 1985;
    (c) the Pendleton Memorial Hospital Record, dated November 12, 1984; and,
    (d) a State Farm Life Insurance form, dated April 26, 1984 and apparently filled out by Dr. Sol B. Stern.

13. The information reported by the Coroner in Bivian Lee's case is consistent with the reported deaths discussed at length in the reports and other literature listed above. Particularly, I am persuaded by Lee's Body Mass Index, indicating that he had lesser stores of body fat. His diastolic hypertension could have been a predisposing factor and made him more vulnerable to arrythmia. If his dietary intake had been severely restricted for some weeks before death, then this would strengthen my opinion. While a dilated and congestive heart, as appears in the autopsy record, may appear to be inconsistent with the syndrome, more sophisticated tissue studies of the heart would help provide more definitive information.

MD
Theodore B. Van Itallie

Sworn to and subscribed before me
this 9th day of May, 1985

Notary Public

My commission expires ______________

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Original Research Communications—general

Cardiac dysfunction in obese dieters: a potentially lethal complication of rapid, massive weight loss[1-3]

Theodore B Van Itallie, MD and Mei-Uih Yang, PhD

ABSTRACT During 1977 and 1978, 17 obese but otherwise healthy adult Americans died suddenly of ventricular arrhythmias during or shortly after completing rapid, massive weight reduction induced by very low-calorie diets consisting largely of collagen hydrolysates for 2 to 8 months. A reexamination of the data on these victims has disclosed a significant positive correlation ($r = 0.824$) between their prediet body mass index and their duration of survival on the very low-calorie diets. Since body mass index reflects degree of fatness, this observation indicates that the ability to defer the lethal effects of severe caloric restriction was a function of the proportion of body fat before dieting. During caloric reduction, the ratio of nitrogen loss to weight loss is inversely related to body fat content; accordingly, we suggest that the fattest dieters survived the longest because they were better able to conserve body (and myocardial) protein. Also, obese people have an enlarged lean body mass which may afford additional protection. *Am J Clin Nutr* 1984;39:695–702.

KEY WORDS Very low calorie diet, liquid protein diet fatalities, ventricular arrhythmias, prolonged QTc interval, body protein depletion, myocardial protein depletion, body fat content, body mass index

Introduction

Regimens that promise rapid weight loss have great appeal for most obese patients. Therefore, severely obese individuals frequently have been treated by total fasting or by very low-calorie (VLC) diets, sometimes referred to as "supplemented fasts" or "protein-sparing modified fasts" (1, 2). For the last 7 yr, VLC diets in packaged form (providing in the range of 300 to 500 kcal/day) have been available to virtually all individuals concerned about their weight. Usually, such diets have been undertaken without the advice or supervision of a physician. Although many obese persons have followed low-calorie diets for prolonged periods without experiencing serious side effects, this excellent safety record should not be permitted to obscure the fact that, under certain conditions, drastic caloric restriction can be extremely hazardous. Herein we call attention to the grave risks that dieters can incur when they undertake regimens that induce rapid, massive weight loss.

Life and death on a VLC diet

In 1977, about 98,000 overweight American women between the ages of 25 and 52 yr used "liquid-protein" products as their sole or principal source of food for at least 1

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month (3) and about 37,000 of them used such products for 2 months or longer. During 1977 and early 1978, 58 deaths were reported in obese adults who were reducing or had recently reduced their body weight by means of diets that provided approximately 300 to 500 kcal/day in the form of collagen or gelatin hydrolysates (4). In some instances, those who died had used protein products of higher biological value (5).

Because of publicity about the deaths, self-prescribed use of liquid-protein products for weight loss decreased dramatically in 1978 and the number of deaths associated with adherence to these diets drastically declined.

After investigating the 58 deaths, the Centers for Disease Control and the Food and Drug Administration (FDA) chose for more intensive examination the cases of 16 white women, ages 23 to 51, and one white man, age 43, who had died unexpectedly of cardiac arrhythmias during or shortly after completing long-term assiduous adherence to VLC diets (5). In contrast to other decedents whose records were incomplete or who suffered from complicating disorders such as diabetes or coronary heart disease, the cases of these 17 victims had been well documented and—except for their obesity—they were judged to have been essentially healthy before dieting. Several summaries of clinical information about this group of fatalities were published in medical journals in 1979 and 1981 (5, 6).

In December 1979, the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology, working under contract with FDA, issued a report (7) to the FDA that reviewed all available information that might have thrown light on the underlying cause(s) of these unexpected deaths. Despite an exhaustive review of the relevant literature and the assistance of many scientific consultants, the LSRO report was unable to establish a specific etiology and pathogenesis of the cardiac complications that had ended the lives of the 17 dieters. In the words of the report (p vii), "the most compelling fact in this review is that 17 basically healthy but obese adults died suddenly and unexpectedly of ventricular tachydysrhythmias associated with prolonged QT intervals and low voltages during or shortly after completing massive, rapid weight reduction by fasting supplemented with protein products. A definite cause-effect relationship could not be established between the use of such products and the deaths."

Regulatory concerns

Concurrently, the FDA had proposed a rule (8) requiring warning statements on protein products (ie, products deriving 50% or more of calories from protein ingredients) that were intended for use (or could be used) as the sole source of nourishment in a weight reduction regimen. Products in this category that provided more than 800 kcal/day were excluded from having to bear the more stringent of two proposed warning statements. In August 1980, a Federal district judge determined that FDA did not have the supporting evidence to require the same statement for products providing between 400 and 800 kcal/day as for those providing 400 kcal or less (9). Accordingly, the entire rule was remanded to the agency for reconsideration. A revised rule (10) was proposed in June 1982 but has not yet been published in final form. At the present time, various weight-reducing diet products providing as little as 330 kcal/day, of which less than 50% are derived from protein, are being promoted to the public without the benefit of an adequate warning label and under conditions in which physicians are unlikely to play a role in selection of candidates for treatment or monitoring of patients during treatment.

This lax approach to severe caloric restriction is partly attributable to the inability of the medical profession to explain why the 17 "otherwise healthy" obese VLC diet adherents died in 1977 and 1978. Theories about the deleterious effects on the heart of poor quality proteins, amino acid imbalance, and deficiencies of various minerals, trace elements, and vitamins were carefully considered and set aside for lack of compelling evidence. Consequently, physicians were left with the impression that the 1977 to 1978 deaths were a unique phenomenon specifically related to the ingestion of collagen/gelatin hydrolysates. Few recalled that (as mentioned earlier) the LSRO report (7) had pointed out that protein supplements of high biological value were used by a few of the victims, indicating that the deaths were *not* exclusively associated with a liquid-protein diet.

Body mass index (BMI) and duration of survival

Recently, we reviewed the LSRO report (7) again and were struck by the following statement in the summary (p vii): "The apparent tendency for the less obese to die sooner than the more obese suggested that a maximum safe period exists for some individuals for this mode of weight reduction and it may vary directly with the degree of obesity."

In order to pursue the implications of this statement, we calculated the prediet BMI for each person who died, and plotted this index, obtained by dividing weight (W) in kg, by height (H) in m^2 [W (kg)/H(m)^2], against months of survival during adherence to the VLC diet (Fig 1). As Figure 1 shows, there is a significant correlation (r = 0.824, SEE = 4.35 wk) between these two variables. Indeed, BMI predicts 68% of the variance in duration of survival on the VLC diet in this group of subjects.

Since BMI reflects degree of body fatness (11), the correlation shown in Figure 1 indicates that the ability to defer the lethal effects of severe caloric restriction was a function of the proportion of body fat at the onset of dieting.

During prolonged starvation the quantity of stored fat generally determines duration of survival (12). Traditional nutritional thinking has it that, when fat stores are totally exhausted, a "premortal" rise in nitrogen excretion occurs, followed by early demise (13). Regardless of the merits of this explanation, it must be pointed out that

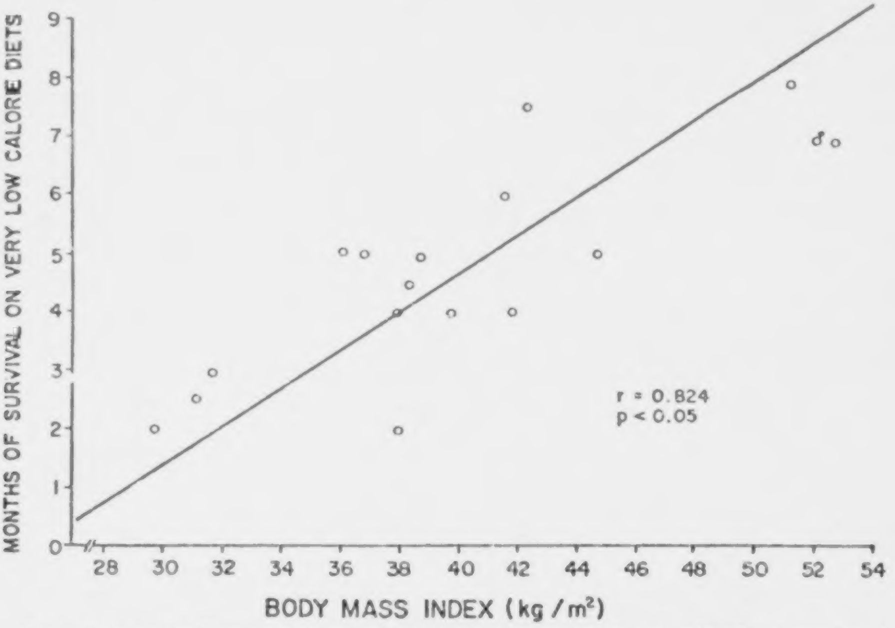

FIG 1. Relationship of duration of survival of 17 obese dieters on VLC diets to prediet BMI. Regression of duration of survival (in months) on BMI for 17 obese persons who died during or shortly after completing prolonged adherence to 300-to 500-kcal diets. The diets usually derived all their energy from tryptophan-supplemented collagen or gelatin hydrolysates. In general, the most obese subjects (as inferred from BMI) survived the longest.

seven of the 1977 to 1978 VLC diet victims were still 20% or more above their desirable weight (14) at the time of death. Moreover, the victims died suddenly of ventricular tachydysrhythmias without passing gradually into the flaccid, comatose state usually exhibited by previously healthy nonobese persons who have starved to death because of lack of food (15).

Possible role of myocardial protein depletion

In our view, the most likely underlying cause of VLC diet deaths was protein depletion, presumably involving the heart. This assertion is based on observations, that date back to 1901 (16), indicating that, during fasting or adherence to a low-calorie diet, the rate at which body protein is lost is largely a function of body fat content during the early stage of caloric restriction. In 1977, we (17) presented data showing that, during caloric restriction, obese persons conserve body protein far more efficiently than nonobese persons do. In 1979, Forbes and Drenick (18) published a review showing that the ratio of nitrogen loss to weight loss for the duration of a fast in humans is an inverse function of body fat, unless the subject has a body fat content in excess of 50 kg. More recently, Durrant et al (19) reported that, in obese patients on a mean intake of approximately 800 kcal/day for 21 days, the ratio of nitrogen loss to weight loss was inversely related to the size of the fat stores of the subjects.

Studies such as these appear to support the contention that the 1977 to 1978 victims' duration of survival on the VLC diets was inversely related to body protein loss. However, we would not want to imply that the quantity of depot fat is the only, or even the principal, determinant of rate of protein loss during severe caloric restriction. Clearly, the composition of a VLC diet can influence nitrogen balance (19). Many other factors affect the ability of an obese individual to conserve protein during prolonged caloric restriction; these include the initial nutritional status of the individual with respect to protein (20), the physical activity level (21), and the capacity to make various endocrine adaptations (22, 23). This discussion focuses on the role of the fat stores in the protein conservation process; however, there is evidence (24) that, on the average, obese adults possess a larger lean body mass and a larger body frame size than nonobese persons of the same sex, age, and stature. Although it is possible that a larger lean body mass is associated with an improved ability to withstand the damaging effects of body protein loss, it is not yet clear how well size of lean body mass correlates with degree of fatness among the obese.

How could body protein loss account for the cardiogenic deaths that occurred in VLC diet victims? Two recent publications throw some light on this putative relationship. Schemmel et al (23) compared protein losses during weight reduction in dietary-obese rats by fasting or by use of a high-protein very low-energy diet. Compared with fasting, use of the high-protein very low-energy diet for short-term weight reduction decreased losses of nitrogen, liver weight, and protein content, as well as kidney weight. However, the high-protein very low-energy diet did not alter losses in body weight, heart weight, heart protein, and heart RNA. If this observation is applicable to human subjects, it would mean that the overall nitrogen-sparing effect of a VLC protein diet vis-à-vis fasting would not necessarily protect the heart from becoming protein depleted and therefore more vulnerable to ventricular arrhythmias.

Nutritional substrate for QT prolongation

Pringle et al (25) described prolongation of the QT interval during therapeutic starvation of obese patients. This study was a retrospective examination of weekly electrocardiograms taken on 13 obese inpatients who fasted for 97 ± 25.4 days (mean ± SD). All of the subjects exhibited a progressive reduction in QRS voltage by the 7th wk. There was a significant prolongation of the QTc interval in the group during the 8th wk and, by the end of the fast, the QTc interval had lengthened beyond normal (> 0.445 s) in seven of the patients. One patient with QTc prolongation experienced two cardiac arrests due to torsade de pointes. [Torsade frequently occurs in the setting of QT prolongation (26).] Of the seven patients who lost more than 30% of body weight, six exhibited pathological QTc prolongation.

In view of the apparent relationship that Pringle et al (25) found between percentage of weight lost and QTc prolongation, note that the mean percentage weight loss of the 17 VLC diet victims was 34.3 (range 12.5 to 44) (7). Only three had lost less than 30% of their initial weight; two of these three had the lowest BMI values of the group.

Of the 17 VLC diet victims, 12 had electrocardiograms taken near the time of death. Of the 10 tracings available for analysis, nine showed low QRS voltage. Accurate measurement of the QT interval was possible in nine cases and the QTc interval in all of them was prolonged (7). (Only one of the victims was known to have had a prolonged QT interval before dieting.)

The heart weights of the victims were decreased in proportion to the documented decreases in body weight, indicating that myocardial mass was not "spared" (6). Histologically, the hearts showed myocardial atrophy, with varying degrees of fiber attenuation, disappearence of myofibrils, excessive lipofuchsin deposition, and absence of significant coronary atherosclerosis (5–7).

As pointed out by Sours et al., myocardial atrophy (the most consistent finding in the VLC diet victims) is fairly specific for protein-calorie malnutrition, both in clinical settings (27, 28) and in animal models (29, 30).

Integration of the foregoing information builds a convincing case that links the VLC diet deaths to myocardial protein depletion, followed by cardiac arrhythmia (see Fig 2). Because degree of fatness apparently influences the body's ability to conserve protein during severe caloric restriction (including fasting), it is difficult to avoid the inference that the high correlation between BMI and duration of survival on the VLC diets reflected the effect of the size of the fat stores on the rate (and, therefore, the quantity) of body protein loss. Therefore, it may be presumed that the fattest dieters survived the longest because they were better able to conserve their body protein. Evidence from other sources suggests that the heart participates in the overall protein loss that occurs during caloric privation (12, 25).

In making this retrospective reconstruction of the events leading to the deaths of the 17 VLC diet victims, we do not wish to suggest that we have accounted for all of the important factors that played a role in causing the terminal arrhythmias. For example, VLC diet-induced changes in the functional state of the autonomic nervous system (31) could have contributed to QT prolongation and the subsequent arrhythmias by creating an imbalance between the various components of the sympathetic innervation of the heart (32). In the so-called acquired long QT syndrome, syncopal attacks and ventricular fibrillation can occur without known precipitating episodes (33). If one considers these factors, together with the known variability in body protein loss exhibited by obese patients who adhere to VLC diets of similar composition for prolonged periods (34, 35), it is somewhat surprising that the correlation between BMI and duration of survival on the VLC diet shown in Figure 1 is as high as it is.

Although little is known about the pathogenesis of the acquired long QT syndrome exhibited by certain persons during and for a variable period of time after prolonged caloric restriction (12), it is likely that severely obese individuals who have lost 30% or more of their body weight rapidly, either by fasting or by means of a VLC diet, are at substantial risk of developing this dangerous cardiac disorder. Less obese persons who reduce their weight rapidly on similar regimens may develop a prolonged QTc interval after losing as little as 10 to 15% of body weight (7, 25). In such individuals, death from ventricular arrhythmia could occur within 2 months of dieting.

Prolongation of the QTc interval was not observed by Lantigua et al (36) in six obese patients who followed a "liquid-protein" diet for 20 to 30 days. In that study, the diet provided 300 kcal/day as hydrolyzed collagen supplemented with tryptophan, calcium, magnesium, phosphorus, potassium, and vitamins. During the treatment period, three of the six subjects exhibited serious arrhythmias, including transient episodes of second degree heart block, frequent ventric-

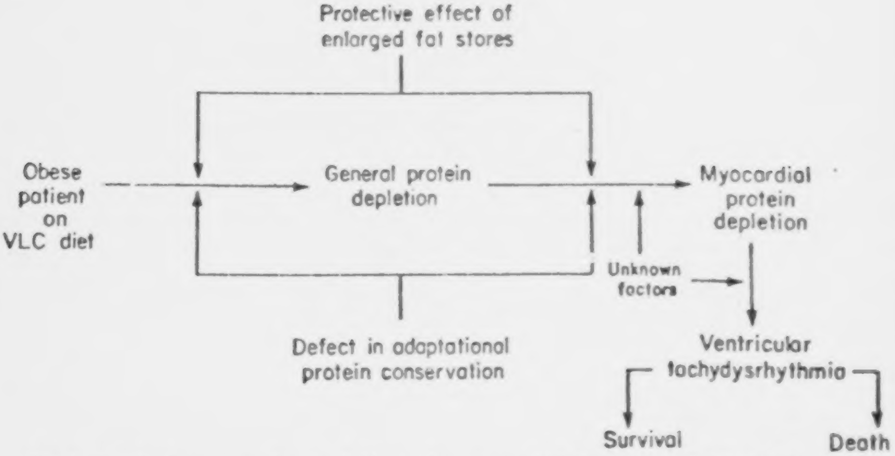
Protective effect of enlarged fat stores
Obese patient on VLC diet
General protein depletion
Myocardial protein depletion
Unknown factors
Defect in adaptational protein conservation
Ventricular tachydysrhythmia
Survival
Death

FIG 2. Postulated sequence of events linking prolonged use of VLC diets to potentially lethal ventricular arrythmias. Obese patients on VLC diets for prolonged periods experience rapid, massive weight loss accompanied by varying degrees of depletion of body and, specifically, myocardial protein. Rate of protein loss is modulated by the size of the fat depot and the ability of the body to call forth adaptational processes that favor protein conservation. Changes in the functional state of the autonomic nervous system, alterations in electrolyte concentrations in plasma and tissues, and other factors, some as yet unknown, also may affect the heart's vulnerability to ventricular arrhythmias.

ular premature contractions, a period of sustained ventricular bigeminy, and an episode of ventricular tachycardia. Total weight loss ranged from 13 to 14.5% of initial weight in the five subjects who completed the 40-day study. The subject who manifested an episode of ventricular tachycardia after 27 days of liquid-protein dieting had lost about 11% of initial weight (which was 160% of desirable weight). It is conceivable that myocardial protein loss played a part in the genesis of at least some of the "liquid-protein diet"-induced arrhythmias reported by Lantigua et al (36).

Conclusion and recommendations

On the basis of available evidence, it seems reasonable to conclude that the 1977 to 1978 VLC diet deaths were not merely idiosyncratic responses to various liquid-protein diets but rather were consequences of a type of cardiac dysfunction that characteristically occurs in a proportion of obese individuals who undergo prolonged, drastic caloric restriction causing rapid, massive weight loss. If this interpretation of the cause of the VLC diet deaths is accepted, even provisionally, physicians and regulatory agencies must consider the implications of this syndrome and take steps to prevent its occurrence. In this regard, all patients who embark on a program of fasting or a VLC diet should be made aware of the risks of prolonged adherence to regimens of this kind and the importance of remaining under a physician's care during such treatment. In particular, dieters should know that the risk of a serious untoward response is greatly increased in mildly or moderately obese persons who undertake drastic weight-reduction regimens.

It is possible that certain morbidly obese patients who experience rapid, massive weight loss after obesity surgery (37) also are at risk of developing cardiac complications. Such patients should be monitored periodically to determine whether the QTc interval is lengthening.

Physicians should discourage mildly or moderately obese individuals from embarking on programs of fasting or VLC dieting. In any case, all patients who adhere to programs of drastic caloric restriction for prolonged periods should be carefully monitored, with electrocardiograms taken weekly.

Finally, the FDA should require those who market VLC diets in packaged form to place appropriate warnings on the labels so that consumers will understand the risks of adherence to such regimens.

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EXHIBIT NO. 10

The Amazing Magic of Natural Herbs

KEYS TO SUCCESSFUL BUSINESS

1. USE ALL OF THE PRODUCTS PERSONALLY.
2. CARE MORE ABOUT YOUR CUSTOMER LOSING WEIGHT THAN THE MONEY YOU MAKE.
3. CARE MORE ABOUT YOUR DISTRIBUTORS AND THEIR PROFIT THAN YOU DO ABOUT YOUR OWN.

REFERENCE POINTS ON NUTRITION

1. 90% OF WHAT PEOPLE SAY IS OPINION.
2. 10% OF WHAT PEOPLE SAY IS FACT.
3. F.D.A. (FOOD AND DRUG ADMINISTRATION)
   - A. THEY DO NOT APPROVE PRODUCTS. THEY ONLY DISAPPROVE PRODUCTS.
   - B. THEY HAVE THREE LISTS:
     - 1) NO NO LIST - DISAPPROVED PRODUCTS.
     - 2) LIST OF INGREDIENTS NOT TESTED LONG ENOUGH.
     - 3) G.R.A.S. LIST (GENERALLY RECOGNIZED AS SAFE)

     ALL OF OUR PRODUCTS ARE ON THE G.R.A.S. LIST !
   - C. MEGA DOSAGE LAW -

     WE MUST ABIDE BY-WARNING OR CAUTION STATEMENTS ARE REQUIRED ON THE LABEL IF ANY PRODUCT WILL BE HARMFUL TO ANY HEALTH PROBLEM OR ANY MEDICATION BEING TAKEN.
4. DON'T BUY THE STORIES PEOPLE FEED YOU. USING THE ABOVE REFERENCE POINTS, YOU HAVE THE ABILITY TO RESPOND IN A PROPER WAY.

   (ALSO, LEARN THE PAGE ON OVERCOMING OBJECTIONS)

• BIGGEST FEAR IN DIETING IS FAILURE ! (THIS IS COVERED IN FOLLOW-UP)

5. BODY NEEDS FOR GOOD HEALTH ON A DAILY BASIS:
   - A. PROTEIN - 40-60 GRAMS.
   - B. CARBOHYDRATES - 100 GRAMS
   - C. VITAMINS AND MINERALS
   - D. FATTY ACIDS - HELP METABOLIZE PROTEIN
   - E. ESSENTIAL OILS (ESPECIALLY UNSATURATED OILS)
6. HERBS CLEANSE THE ENTIRE SYSTEM (BLOOD AND DIGESTIVE) SO THAT THESE FIVE ESSENTIAL THINGS NEEDED FOR GOOD HEALTH CAN BE ABSORBED. WHEN THE BODY IS NOT FUNCTIONING PROPERLY, YOU CANNOT FIGHT DISEASE.
7. TOXINS ARE CHEMICAL INGESTED THROUGH THE FOOD WE EAT AND DRINK:
   - A. ADDITIVES
   - B. PRESERVATIVES
   - C. SPRAYS
   - D. CHEMICALS USED IN THE PROCESSING OF FOODS (IE. ORANGE JUICE, ETC.)

8. BODY GETS RID OF TOXINS THROUGH:

   A. BREATHING
   B. SKIN
   C. MOUTH
   D. ELIMINATION

9. ONE PERSON IN TWENTY WILL HAVE PROBLEMS WHEN THEY BEGIN ON THE PROGRAM BECAUSE THEIR BODIES ARE FULL OF TOXINS. THESE ARE THE COMMON SYMPTOMS WHEN THE BODY IS HAVING TROUBLE GETTING RID OF TOXINS:

   A. DIARRHEA
   B. CONSTIPATION
   C. HEADACHE
   D. NAUSEA
   E. BREAKOUTS

   * USE OF ALOE JUICE WILL DECREASE THESE PROBLEMS TO 1 IN 40.

   IF YOU DO NOT PUT UP WITH THE DISCOMFORT OF GETTING THE TOXINS OUT, YOU WILL HAVE DISEASE LATER.

   READ THE DR. STANLEY BASS LETTER

10. EVERY 120 DAYS YOUR BODY REPLACES CELLS. BODY IS MADE UP OF PROTEIN CELLS. YOU MUST HAVE PROTEIN TO SUSTAIN LIFE. THE BODY WILL EAT ITSELF TO STAY ALIVE. MANY DIETS ARE NOT BALANCED AND ACTUALLY DO MORE DAMAGE THAN GOOD BECAUSE THEY TAKE WEIGHT FROM VITAL ORGANS INSTEAD OF FROM THE FAT CELLS. THE BODY WILL EAT ITSELF TO STAY ALIVE.

11. PROTEIN IS MADE UP OF AMINO ACIDS. AMINO ACIDS IN DIFFERENT COMBINATIONS SUPPLY THE RIGHT PROTEIN TO EVERY CELL.

    22 AMINO ACIDS ARE NEEDED TO ACCOMPLISH THIS.

    14 AMINO ACIDS CAN BE PRODUCED NATURALLY IN THE BODY.

    8 AMINO ACIDS MUST BE GOTTEN FROM AN OUTSIDE SOURCE.

WHO CAN USE THESE PRODUCTS ? ALL PEOPLE WHO CAN EAT FOOD!!!

THESE PRODUCTS SUPPLY ALL THE NUTRIENTS YOU NEED IN BALANCE ON A DAILY BASIS. USING THE PROPER DOSAGES, BABIES, ELDERLY, PEOPLE WITH HEALTH PROBLEMS, ON MEDICATION, ETC. CAN USE THE PRODUCTS.

REMEMBER: THE PRODUCTS ARE JUST LOW CALORIE FOOD!

FLORA FIBER

1. IT REPLACES THE FLORA THAT IS RUNNING THROUGH THE GI TRACT OF YOUR BODY WHICH IS VERY IMPORTANT TO YOUR SYSTEM.

2. IT HELPS TO SCRUB AND CLEANSE THE INTESTINAL TRACT.

3. HELPS TO CONTRIBUTE TO A WELL-BALANCED DIET.

PRIMARY INGREDIENT IS LACTOBACILLUS ACIDOPHILUS WHICH IS A TINY SINGLE ORGANISM FOUND IN YOUR GI TRACT.

YOU MUST HAVE A CERTAIN AMOUNT OF BACTERIA IN YOUR BODY SO THAT YOU DO NOT CATCH CERTAIN DISEASES THAT CAUSE POOR HEALTH. IT HELPS COMBAT DISEASE. IT REPLACES THE INTESTINAL FLORA IN YOUR BODY SO YOU DO NOT CATCH DISEASE.

IT HAS VERY RICH SOURCES OF FIBER. AS IT MOVES THROUGH THE INTESTINAL TRACT IT PUSHES ALL THE IMPURITIES IN YOUR BODY OUT THROUGH THE COLON.

K-8

1. HELPS STRESS INDUCED DEPRESSION.

2. HELPS TO ELEVATE YOUR MOOD SO YOU CAN HANDLE THAT STRESS.

PRIMARY INGREDIENT IS BIO KAWA.
HELPS TO NORMALIZE THE THREE NEURO HORMONES THAT ARE IN YOUR BRAIN TO ELEVATE YOUR MOODS SO THAT YOU CAN HANDLE STRESS IN YOUR LIFE AT WHATEVER LEVEL IT'S AT...

SCHIZANDRA

MUCH RESEARCH HAS BEEN DONE ON THE BIOLOGICAL FACTORS THAT CONTRIBUTE TO THE AGING PROCESS. UNTIL RECENTLY, THE BODILY DETERIORATION THAT COMES WITH AGE HAS BEEN ACCEPTED AS JUST THE INEVITABLE EFFECT OF THE PASSING OF TIME. NOW WE KNOW THAT THE AGING PROCESS IS LARGELY THE EFFECT OF CELLULAR BREAKDOWN. VARIOUS FACTORS CONTRIBUTE TO CELLULAR BREAKDOWN, BUT THERE ARE CERTAIN NUTRIENTS--KNOW GENERALLY AS ANTI-OXIDANTS--THAT COMBAT THE CAUSES OF THIS DETERIORATION.

SCHIZANDRA CONTAINS THESE ANTIOXIDANT NUTRIENTS, AND, OF COURSE, THE HERB SCHIZANDRA (SCHIZANDRA CHINENSIS).

DISCOVERED OVER 4,000 YEARS AGO, THIS HERB HAS BEEN CALLED AN "ADAPTOGEN" BECAUSE OF ITS ABILITY TO HELP THE BODY ADAPT TO ADVERSE CONDITIONS. THERE IS A UNIQUE HEALING SUBSTANCE FOUND IN IT'S BERRY-LIKE FRUIT THAT BUILDS AN OVERALL RESISTANCE TO UNHEALTHY INFLUENCES. RATHER THAN HEALING ONE SPECIFIC AREA OF THE BODY, SCHIZANDRA CREATES A "STATE OF NONSPECIFIC INCREASED RESISTANCE", A PHRASE COINED BY A RUSSIAN RESEARCHER, N.V. LAZAREV.

RESISTANCE TO STRESS AND DISEASE, INCREASED ENERGY AND MUSCULAR ACTIVITY, NOURISHMENT FOR VISCERA (INTESTINES), IMPROVED VISION, AND THE STIMULATION OF HEALING TO THE ENTIRE BODY ARE ALL BENEFITS ATTRIBUTED TO SCHIZANDRA.

AMERCIANS ARE ONLY BEGINNING TO LEARN ABOUT SCHIZANDRA, AS IT HAS ONLY RECENTLY BEEN MADE AVAILABLE TO THE GENERAL PUBLIC. THE CHINESE HAVE KNOWN OF IT'S ALMOST MAGICAL QUALITIES FOR THOUSANDS OF YEARS, AND THE RUSSIANS AND SWEDES HAVE BEEN USING IT FOR SEVERAL DECADES.

SCIENTIFIC DATA HAS BEEN MULTIPLYING DUE TO THE MANY POSITIVE EFFECTS OF SCHIZANDRA. IN 1969, IN THE TOWN OF CHRICHIK OF THE TASHKENT REGION OF THE USSR, AN INFLUENZA EPIDEMIC WAS RAGING. A TEST WAS CARRIED OUT ON 559 CHILDREN WHO WERE SPLIT INTO TWO GROUPS. ONE GROUP RECEIVED SCHIZANDRA; THE OTHER DID NOT. AFTER A PERIOD OF TIME, THE GROUP RECEIVING SCHIZANDRA WAS FOUND TO HAVE A GREATER RESISTANCE TO INFLUENZA THAN THE GROUP DEPRIVED OF THIS DYNAMIC NUTRIENT.

WE MAY FIND THAT THIS LEGENDARY ADAPTOGEN HOLDS THE KEY TO PRESERVING A LONGER MORE FRUITFUL LIFE. BECAUSE SCHIZANDRA IS RARE AND ONLY FOUND IN CERTAIN REMOTE AREAS (TIBET, CHINA AND RUSSIA), IT IS AVAILABLE IN THE UNITED STATES, BUT IN LIMITED QUANTITIES.

TWO TABLETS, ONE IN THE MORNING AND ONE IN THE EVENING IS THE RECOMMENDED DOSAGE.

*FOR A MORE DETAILED GUIDE THAT EXPLAINS THE DIFFERENT THEORIES ON AGING AND THE NUTRIENTS THAT COMBAT THEM SEND FOR DR. RICHARD MARCONI'S BOOKLET, "LET'S GROW YOUNGER". SCIENTIFIC NUTRITION PRESS
P.O. BOX 3572
SEAL BEACH, CA 90740

$1.95 EACH, PLUS 50¢ FOR SHIPPING ($1.00 FOR 2 OR MORE)

PRODUCT KNOWLEDGE

SLIM AND TRIM

FORMULA #1 - PROTEIN POWDER

1. PROVIDES 18 AMINO ACIDS, INCLUDING 8 ESSENTIAL AMINO ACIDS. THE OTHER 4 AMINO ACIDS WILL BE PRODUCED WITH THE 18 IN BALANCE.

2. HIGH QUALITY VEGETABLE PROTEIN.

3. CAUSES THE BODY TO BURN FAT.

4. MARK THE CONTAINER SO THAT THE CUSTOMER WILL REMOVE ¼ OF THE POWDER.

   WRITE THE WORDS SHAKE ON THE CAN, AND BE SURE THE CUSTOMER UNDERSTANDS THAT THEY SHOULD USE LEVEL TABLESPOONS!

5. 2 SHAKES PER DAY IN PLACE OF TWO MEALS ----- LOSE

   1 SHAKE PER DAY IN PLACE OF ONE MEAL ----- MAINTAIN

   3 SHAKES PER DAY WITH MEALS ----- GAIN

6. SHAKES WILL PROVIDE UP TO 200 CALORIES PER MEAL.

   2 T. SHAKEN POWDER = 70 CALORIES
   NON-FAT MILK = 95 CALORIES
   FRUIT = 35 CALORIES

   200 CALORIES

   NEED TO KEEP TOTAL CALORIE INTAKE AT 1,000 CALORIES PER DAY IN ORDER TO LOSE WEIGHT. IF YOU DO NOT LOSE ON 1,000 CALORIES, THERE IS A PROBLEM IN DIGESTION (BODY FUNCTION).

7. CHILDREN MAY USE THE POWDER (1 TABLESPOON PER 80 LBS. BODY WEIGHT).

   E.G. A 40 LB. CHILD WOULD USE ½ TBLSPN.

FORMULA #2 - HERB TABLETS

1. 14 HERBS THAT NATURALLY SUPPRESS THE APPETITE. CLEANSES BOTH THE BLOOD AND DIGESTIVE SYSTEM OF TOXINS.

2. WILL CLEANSE THE TOXINS THAT ARE NOT DIGESTED AND ARE STORED IN THE FATTY TISSUE.

3. 2 TABLETS 3 TIMES A DAY ------ LOSE
   2 TABLETS 3 TIMES A DAY ------ MAINTAIN
   3 TABLETS 2 TIMES A DAY AFTER 1ST AND 3RD MEAL ------ GAIN

4. IF HUNGRY BETWEEN MEALS, INCREASE TO 4 AT EACH MEAL.

5. CHILD'S DOSAGE: 60 LBS. AND OVER USE AS ADULT
   25-60 LBS. USE 1 TABLET THREE TIMES A DAY.

FORMULA #3 - VITAMINS AND MINERALS

1. FORMULA #3 HAS EVERY VITAMIN, MINERAL AND TRACE MINERALS THAT THE BODY LOSES EVERY DAY THROUGH NORMAL ELIMINATION.
2. MEGA DOSAGES ARE NOT NECESSARY (IF COLON IS CLEAR) FOR PROPER ABSORPTION.
3. TAKE 1 TABLET 3 TIMES PER DAY TO LOSE, MAINTAIN, OR GAIN.
4. VEGETABLE PROTEIN COATING HELPS YOU METABOLIZE THE PRODUCT.
5. CHILD'S DOSAGE: SAME AS ADULT FOR CHILD OVER 60 LBS.
25-60 LBS. USE ½ TABLET 3 TIMES A DAY.

FORMULA #4 - OIL

1. OIL CAPSULE THAT HELPS TIGHTEN THE SKIN AS YOU ARE LOSING WEIGHT.
2. SUPPLIES ESSENTIAL FATTY ACIDS WHICH AID IN THE DIGESTION AND ASSIMILATION OF PROTEIN.
3. CARRIES OIL SOLUABLE VITAMINS (A,D,E, & K) THROUGH THE SYSTEM AND HELPS THE BODY TO USE THEM.
4. TAKE 1 CAPSULE 3 TIMES A DAY TO LOSE, MAINTAIN, OR GAIN.
5. CHILD'S DOSAGE: 1 CAPSULE THREE TIMES A DAY FOR WEIGHTS ABOVE 25 LBS.

ALOE JUICE

1. AIDS IN DIGESTION AND ACCELERATES WEIGHT LOSS.
2. FINEST CLEANSER AND HEALER OF DIGESTIVE TRACT.
3. A LIVE PRODUCT, 92% FREE-FLOWING ENZYMES. NO WATER ADDED OR THICKENING AGENTS ADDED. THE LEAVES OF THE ALOE VERA PLANT ARE HAND-FILLETED TO PREVENT BITTERNESS. ONLY THE INSIDE OF THE PLANT IS USED. IT HAS BEEN STABLIZED WITH HERBS AND CONTAINS NO PRESERVATIVES, NATURAL OR OTHERWISE.
4. BECAUSE IT IS LIVE, IT HAS A 30-DAY SHELF LIFE WHEN OPENED. 6 MONTH SHELF WHEN SEALED.
5. DO NOT EXPOSE TO EXCESSIVE HEAT (BE CAUTIOUS OF LEAVING IN YOUR CAR DURING THE SUMMER)
6. WHEN YOU ARE HAVING A PROBLEM WITH NOT LOSING AND ARE CONSUMING ONLY 1,000 CALORIES A DAY, YOUR BODY IS NOT FUNCTIONING PROPERLY IN THE AREA OF FOOD DIGESTION AND ASSIMILATION. HERBAL ALOE WILL HELP AID THE DIGESTION AND ASSIMILATION BECAUSE IT CLEANSES YOUR SYSTEM.
7. DRINK 2-4 OZ. BEFORE YOUR BULK MEAL.
8. PEOPLE WITH PROBLEMS: 2-4 OZ BEFORE EACH MEAL (MINIMUM).
9. MAKES EVERYTHING IN THE SLIM AND TRIM PROGRAM WORK FASTER.
10. DRINK AS MUCH AS YOU CAN AFFORD!
11. DUE TO VARYING SOILS AND CLIMATIC CONDITIONS, ALOE VERA MAY OCCASIONALLY VARY SOMEWHAT IN FLAVOR. THE TASTE DIFFERENCE IN NO WAY AFFECTS THE QUALITY OF THE PRODUCT. THE PROPERTIES, INGREDIENTS, AND PERCENTAGES ARE ALWAYS CONSTANT. "IT'S LIKE TOMATOES, NO TWO EVER TASTE THE SAME".

NATURAL RAW GUARANA

1. GUARANA NATURALLY INCREASES ENERGY, MENTAL ALERTNESS, AND PROVIDES A NATURAL LIFT.
2. NORMALIZES ADRENAL GLANDS AND BRINGS ADRENAL FLOW UP OR DOWN AND STABILIZES IT IN THE BLOOD STREAM. CAFFEINE IS A CHEMICAL STIMULANT THAT CAUSES STRESS IN OUR CENTRAL NERVOUS SYSTEM AND CAN CAUSE OTHER SERIOUS PROBLEMS IN OUR BODY N.R.G. WORKS IN THE ADRENAL SYSTEM WHERE NATURAL ENERGY IS PRODUCED.
3. CAN BE EFFECTIVE IN SOME TYPES OF ALLERGIES AND ASTHMA WHERE THE BODY PRODUCES EXCESSIVE HISTAMINES. SLUGGISH ADRENALS CANNOT ABSORB THESE HISTAMINES ADEQUATELY SO ANTIHISTAMINE DRUGS ARE USED TO REGULATE THE PROBLEM.

CELLULITE PRODUCT

1. CELLULITE IS CAUSED FROM A COMBINATION OF FLUID TRAPPED IN FAT CELLS AND POOR CIRCULATION (THE LESS CIRCULATION, THE HARDER THE FAT CELL BECOMES.) TOXINS ARE STORED IN FATTY TISSUE CAUSING A BUILD UP OF FLUIDS.
2. CELLULITE SHOWS MORE ON WOMEN BECAUSE THEIR OUTER THREE LAYERS OF SKIN ARE THINNER THAN MEN'S.
3. OXYGEN HELPS TO BREAK UP FAT CELLS.
4. INCREASES CIRCULATION PROVIDING ADEQUATE OXYGEN. THIS PRODUCT IS GOOD FOR SOMEONE WITH GENERALLY BAD CIRCULATION (COLD HANDS AND FEET).
5. CONTAINS 6 HERBS THAT HAVE A DIRUETIC EFFECT ON THE CELLS SO IT ELIMINATES EXCESS FLUIDS AND PROVIDES YOU WITH INCH LOSS.
6. 3 TABLETS PER DAY RECOMMENDED. MAXIMUM OF 4 BECAUSE OF LARGE POTASSIUM CONTENT AND POTASSIUM IS NOT WATER SOLUABLE.
7. COMPLETE SMOOTHING OF CELLULITE NORMALLY TAKES ABOUT 5-6 MONTHS.

SOUPS - BEEF FRENCH ONION CHICKEN

1. 80 CALORIES PER SERVING.
2. SODIUM (SALT) FREE- MUST BE SEASONED TO TASTE.
3. CAN BE USED FOR GRAVIES AND DIPS. TRY THE CHICKEN SOUP AS A COATING ON CHICKEN.
4. CONTAINS 7 HERBS FOR GOOD HEALTH.
5. A UNIVERSITY STUDY HAS SHOWN THAT SOUP, RATHER THAN SALAD, BEFORE A MEAL CAN AID IN WEIGHT LOSS.

TANG KUEI - (PRONOUNCED DON QUAI)

1. HERB FROM CHINA, AGED 7 YEARS TO PRODUCE EFFECTIVENESS.
2. RELIEVES MENSTRUAL DISORDERS
   - A. EFFECTIVE FOR MENOPAUSE
   - B. RELAXES AND STRENGTHENS INTERNAL ORGANS AND MUSCLES. GREAT FOR ATHLETES, ANYONE WHO EXERCISES, PROBLEMS CAUSED FROM TENSION.
3. OB/GYN DOCTORS RECOGNIZE AND USE THIS HERB AS AN EFFECTIVE TREATMENT FOR FEMALE PROBLEMS.
4. PROVIDES RELIEF FOR MIGRAINE HEADACHES. TAKE THREE TABLETS WITH SOME HERBAL ALOE FOR BEST RESULTS.
5. FOR MENSTRUAL CRAMPING:

   9 TABLETS THE FIRST DAY (3- THREE TIMES A DAY)
   7 TABLETS THE SECOND DAY
   5 TABLETS THE THIRD DAY
   3 TABLETS THE FOURTH DAY

   TAKE ONE OR TWO DAILY THROUGHOUT THE MONTH. THE SECOND MONTH, START WITH 7 TABLETS THE FIRST DAY. THIS IS NECESSARY TO DISCOVER WHAT AMOUNT WILL GIVE BEST RESULTS.
6. TANG KUEI CANNOT BE TAKEN WITH VITAMIN C. VITAMIN C DESTROYS THE ACTIVITY OF THE HERB. TAKE 2 HOURS BEFORE OR AFTER VITAMIN C. DO NOT USE A TIME-RELEASED VITAMIN C WHEN TAKING TANG KUEI.
7. FOR MENOPAUSE, TAKE 2-4 TABLETS ALONG WITH 4-6 OZ. OF HERBAL ALOE.
8. WORKS FASTER IF YOUR TAKE SOME ALOE JUICE WITH TANG KUEI.
9. SLEEP AID AND MUSCLE RELAXANT. TAKE 2-3 TABLETS WITH HERBAL ALOE BEFORE BEDTIME.

SKIN CARE PROGRAM

HERBAL FORMULATION (NOT JUST FRAGRANCED) SO YOU GET HEALTHY, HEALING EFFECTS. ALOE IS THE BASE FOR THE SKIN CARE PROGRAM.

FORMULA #1 - CLEANSER

1. REMOVES BOTH WATER SOLUABLE WASTES FROM SURFACE OF FACE AND OILY SUBSTANCES FROM THE SKIN (INCLUDING THE PORES).
2. THE DIRT THAT ACCUMULATES ON YOUR FACE (WASTES AND OILS) CAUSES LARGE PORES AND BLEMISHES ON YOUR SKIN.
3. EXCELLENT LUBRICANT FOR SHAVING.
4. REMOVE THE CLEANSER WITH A WARM, WET WASHCLOTH.

FORMULA #2 - SCRUB

1. MADE FROM GROUND CORN COB MEAL. SO MILD IT CAN BE USED DAILY ON MOST SKIN TYPES. DRY, SENSITIVE SKIN MAY ONLY REQUIRE TWICE A WEEK.
2. USE IT IMMEDIATELY AFTER CLEANSING.
3. REMOVES DEAD SKIN CELLS, STIMULATES NEW CELL GROWTH, PROVIDING A NATURAL SHEEN AND SMOOTH TEXTURE TO THE SKIN.
4. MASSAGE SCRUB ON FACE AND NECK FOR 2-3 MINUTES.
5. REMOVE WITH WARM, WET WASHCLOTH.
6. INCREASES CIRCULATION IN THE SKIN.

FORMULA #3 - TONER AND BALANCER

1. STIMULATES AND BALANCES SKIN BACK TO A NORMAL PH LEVEL.
2. REMOVES EXCESS RESIDUE AND SOOTHES SKIN.

FORMULA #4 - DAYTIME MOISTURIZER

1. BASED WITH COLLAGEN PROTEIN, WHICH WITH THE AID OF HERBS, PENETRATES THREE LAYERS OF SKIN.
2. HEALS, PROTECTS, SOFTENS AND MOISTURIZES THE SKIN.
3. PROTECTS SKIN FROM THE HARSH ELEMENTS. FACE IS ONLY PART OF OUR BODY THAT HAS CONTINUAL EXPOSURE BOTH SUMMER AND WINTER TO THESE DAMAGING ELEMENTS.

REJUVENATING CREME

1. RESTORES ELASTICITY TO THE SKIN.
2. DIMINISHES WRINKLES.
3. SOFTENS AND PROTECTS THE SKIN.
4. BASED WITH COLLAGEN AND ELASTIN PROTEIN.
5. GREATEST NEED FOR MOISTURE, ELASTIN AND COLLAGEN IS AT NIGHT WHEN THE NUTRIENTS ARE IN SHORTER SUPPLY BECAUSE OF A SLOW DOWN IN THE BLOOD SYSTEM WHICH SUPPLIES THEM.
6. CLEANSE FACE, USE TONER/BALANCER, THEN APPLY REJUVENATING CREME.
7. HERBS HELP PROTEIN TO PENETRATE 7 LAYERS OF SKIN.
8. COLLAGEN PROTEIN PRESENT TO SMOOTH OUT UNDESIRABLE WRINKLES AND DIMINISH PREMATURE AGING.

HERBAL SHAMPOO AND RINSE

1. HERBAL FORMULATED (NOT FRAGRANCED).
2. BRINGS HEALTHY BENEFITS OF HERBS TO YOUR HAIR AND SCALP.
3. BRINGS OUT NATURAL COLOR AND HIGHLIGHTS.
4. HELPFUL IN HEALING MANY SCALP PROBLEMS.

ALOE GEL

GOOD FOR ANY TYPE OF SKIN IRRITATION SUCH AS INSECT BITES, SCRAPES, BURNS, CUTS, AND ABRASIONS.

ARTHRITIC PAIN RELIEVER

TEMPORARILY RELIEVES THE PAIN FROM ARTHRITIS, SOOTHES AND RELIEVES INFLAMMATION. CAN BE HEALING TO WOUNDS.

CARDIOVASCULAR PRODUCT

DESIGNED TO SUPPLY MANY OF THE NUTRITIONAL FACTORS ESSENTIAL FOR ACHIEVING AND MAINTAINING A HEALTHY CARDIOVASCULAR SYSTEM.

PUBLISHED SCIENTIFIC STUDIES THROUGHOUT THE WORLD INDICATE THAT THE NUTRIENTS IN THIS PRODUCT HAVE AIDED IN:

1. NORMALIZING BLOOD PRESSURE.
2. REDUCING PLASMA CHOLESTEROL.
3. LOWERING TRIGLYCERIDES.
4. ALLEVIATING THE ABNORMAL BUILD-UP OF PLAQUE IN THE ARTERIES.
5. PROVIDING NUTRITION FOR THE PROTECTION OF THE ENTIRE VASCULAR SYSTEM.
6. DOSAGE: 9 TABLETS PER DAY FOR PEOPLE WITH HEART DISEASE.
   3 TABLETS PER DAY FOR PREVENTATIVE USE.

HERBAL CHILDREN'S MULTI-VITAMIN

AN HERBAL MULTI-VITAMIN FORMULA FOR INFANTS AND CHILDREN. . IT IS THE ONLY MICELLIZED MULTI-VITAMIN FORMULA WITH HERBS FOR CHILDREN IN THE WORLD. THROUGH THIS MICELLIZATION PROCESS, FAT SOLUABLE VITAMINS ARE TURNED TO A CONDITION SIMILAR TO WATER SOLUABLE VITAMINS;THEREFORE, VITAMINS A,D, & E ARE MORE EFFECTIVELY ABSORBED INTO THE BODY OF AN INFANT OR CHILD.

IT IS A PLEASANT-TASTING LIQUID WITH NO ARTIFICIAL FLAVORS OR COLORS.

HINTS TO HELP YOU LOSE

1. Start off your bulk meal with hot soup. Preferably beef broth, chicken broth or consomme. It is a good appetite spoiler and in recent university studies has been proven a real aid in weight loss.

2. Save calories for the time of day when you most need them and they give you the most pleasure.

3. Shakes have 200 calories each. So in order for you to stay at 1000 calories per day, your bulk food should not exceed 600 calories, including any snacks.

4. Don't depend on food for most of your rewards. Make a point of scheduling other daily pleasures for yourself like a get-away-from-it-all swim or walk or a half hour reading time so you won't look to food as your only gratification.

THE INCREDIBLE 100-CALORIE CHART

100 calories can get you a lot of food --- or very little.

FOOD	MEASURE
asparagus	3½ cups
banana	1 medium
beef, lean ground	1 3/4 ounces
bean sprouts	3 cups
broccoli, fresh	2½ cups
bread, whole wheat	2 slices
canteloupe	1 small
chicken, white meat	2 ounces
cheese (swiss, cheddar)	1 ounce
eggs, whole large	1½ egg
fish, filet of sole	4½ ounces
mushrooms	5 cups
orange juice, fresh	1 cup
peanut butter	1 tablespoon
potato, baked	1 small
popcorn, lightly salted	2½ cups
raspberries	1½ cups
spinach, fresh	4½ cups
strawberries, frozen	2 cups
tomatoes	3 medium
zucchini	5 cups

5. Eat what you genuinely like---and avoid what you really detest. To be successful on a diet, you need to retain those flavors, textures and fragrances that you enjoy. The way to cut calories is simply to eat less of those favorites. Try the spaghetti as a side dish, served on a salad plate, in combination with clear soup and a green salad. If you have a realy sweet tooth, indulge---save your calorie allotment so you can enjoy a small piece of cake.

TIPS FROM YOUR HERBALIFE CONSULTANT

1. Shake the can of protein powder each time you measure or you will be getting more calories than you need. Remember to use level tablespoons.

2. Drink at least 8 glasses of water each day. This helps to flush out the excess fluid in our systems.

3. Remember to take your tablets 3 times a day -- once with each meal. If you forget double up on them, but get in the recommended amount for each day.

4. If you have a problem with constipation, increase your water intake and take Herbal Aloe. (2-4 ounces before each meal -- with shakes and bulk meals)

5. Remember - the purpose of this program is to lose your weight and to establish a lifetime of good health and staying slim.

6. Call me if you have any questions or if you are finding yourself struggling with dieting. The first week or two of a diet is always the hardest. But with this program, you will be feeling so good within a week or two that you will be encouraged and the diet will seem much easier to stay on.

7. Take it one day at a time. The first week you need to write down everything you eat, including every morsel that you nibble on. This will help you to accurately evaluate your weight loss. Remember, this program will work for you if you follow it.

8. If you feel you need extra energy, try our N.R.G.

9. Try to increase your physical activity.

RECIPES (using blender)

Prefreeze milk in ice trays.

3-4 milk cubes
8 oz. milk (nonfat)
Protein Powder

Add any of the following:
Any fresh or frozen fruit
½ of a banana, fresh or frozen
½ envelope of ALBA 77 chocolate
(or strawberry flavor)

8 oz. fruit juice (apple, cranapple, orange, etc.)
3-4 frozen strawberries (or other fruit)
½ banana, fresh or frozen
Protein Powder

2 Tbsp. each:
frozen pineapple juice concentrate
frozen orange juice concentrate
nonfat dry milk
1 cup water
½ banana, fresh or frozen (optional)
Protein Powder

3 Tbsp. frozen orange juice concentrate
8 oz. water
2 Tbsp. nonfat dry milk
Protein Powder

PROTEIN POWDER CAN BE BLENDED OR STIRRED IN ANY FRUIT JUICE OR JUST PLAIN MILK.

IT'S GREAT IN YOGURT!

WHAT SYMPTOMS TO EXPECT
WHEN YOU IMPROVE YOUR DIET

by

Dr. Stanley S. Bass, N.D., D.C., Ph.C.

If I were asked which is the area of greatest misunderstanding and confusion in the field of nutrition, I would immediately be forced to reply, it is the failure to properly understand interpret the symptoms and changes which follow the beginning of a better nutritional program.

What is meant by a better nutritional program? It is the introduction of foods of higher quality in place of lower quality ones. For example, if a person replaces a protein rich food such as pork with beef, the beef may be considered the superior of the two due to its easier digestibility, lower and less saturated fat content, etc.; chicken is superior to beef and fish is superior to chicken because of its more rapid digestibility and lower saturated fat content. Lima beans, lentils or chick peas, which are eaten at the same meal with vegetables, are superior in all the nutrients needed to rebuild health. As we go higher in the scale of quality, we begin to include protein rich food which may be eaten in the unfired state, such as cheese which is made from raw milk and unsalted. Then we ascend to the nuts and seeds which are eaten in the natural state (raw and unsalted). To summarize: the closer the food comes to the natural state in which it occurs, or the closer we come to its raw, unfired form, the higher its quality. In this condition, all the enzymes are found intact. The amino acids are in their finest form. The minerals, vitamins, trace elements, carbohydrates and "life force" are present. The life force, in turn, is capable of reproducing healthy tissue.

This same classification of quality which we analyzed in relation to protein rich foods applies to the carbohydrates (the starches and sugar-rich foods), the fats and the mineral-rich foods.

The quality of a nutritional program is also improved by OMITTING toxic substances such as coffee, tea, chocolate, tobacco, salt, pepper, etc.

What is the relation of quality of foods to recovery from illness? It is this in a nutshell: the HIGHER the quality of food is that we eat, the QUICKER we recover from disease provided we are able to properly digest and assimilate properly. To this must be added the knowledge of (a) proper food combining, (b) proper order of eating the different kinds of food at a meal; e.g., the most easily digested food should be eaten first, the more complex one second, and the most concentrated item last, (c) the correct quantity of food to be consumed (of each type) in the meal, and (d) the correct time for eating (when hungry, and not by the clock).

Now, what happens when a person follows these rules and makes a decided improvement in the quality of the food consumed? Remarkable things begin to happen to the body as well as the mind. The amazing intelligence present in every cell of the body and the wisdom of the body in its operation immediately becomes manifest. The rules may be stated thusly: when the quality of the food coming into the body is of higher quality than the tissues which the body is made of, the body begins to discard the lower grade meterials and tissues to make room for the superior materials which it uses to make new and healthier tissue. This is the plan of NATURE. The body is very selective and ALWAYS aims for improvement for better health. The body ALWAYS tries to produce health and ALWAYS will, unless our interference is too great. Only then do we fail to recover and degenerate further into disease. The self-curing nature of many conditions such as colds, fevers, cuts, swellings, injuries, etc., furnishes endless examples of how the body tends towards health--ALWAYS--unless we do something to stop the process.

What are the symptoms or signs which become evident when we first begin to omit the lower grade foods and instead introduce superior foods---those which are more alive, more natural than we are accustomed to? When the use of a toxic stimulant such as coffee, tea, chocolate or cocoa is suddenly stopped, headaches are common and a letdown occurs. This is due to the discard by the body of the toxins called caffeine and theobromine which are removed from the tissues and transported through the blood stream during its many bodily rounds. Before the noxious agents reach their final destination for elimination, these irritants register in our consciousness as pain--in other words, headache. The letdown is due to the slower action of the heart--the resting phase which follows the stimulation of more rapid heart action forced upon the body by certain poisons called stimulants. The more rapid heart beat (or pulse) produces a feeling or exhilaration, and the slower action produces a depressed state of mind. Usually, within three days, the symptoms vanish and we feel stronger due to the recuperation which follows.

To a lesser extent, the same process occurs when we abandon lower quality foods and replace them with better foods. Lower quality foods have undergone more preparation. Spices, salt and other ingredients have been added, as they ten to be more stimulating than less prepared and more natural foods. Animal foods such as meat, fowl, fish, etc. are more stimulating than cheese, nuts and vegetable proteins. Consequently, the withdrawal of stimulation which follows the abandonment of animal food produces a slower heart action---a resting phase---which registers in the mind as relaxation or a decrease in energy. This inital letdown lasts about ten days or slightly longer and is followed by an increase of strength, a feeling of diminishing stress and greater well-being.

Now, let us return to the symptoms which occur in the process of regeneration.

The person who starts a better diet, stays on it for three days to a week and then quits will say, "Oh! I felt better on the old diet--the new one made me feel weak." He failed because he didn't give his body a chance to adjust and complete its first phase of action--recuperation. If he had waited a while longer, he would have begun to feel better than before he started.

During this initial phase (lasting about ten days on the average to several weeks in others), the vital energies which are usually in the periphery or external part of the body such as the muscles and skin, begin to move to the vital internal organs and start reconstruction. This shunting of much of the power to the internal region produces a feeling to less energy in the muscles, which the mind interprets as some weakness. Actually, the power is increased, but most of it is being used for rebuilding the more important organs and less of it is available for muscular work. Any weakness which is felt here is not true weakness, but merely a redeploying of forces to the more important internal parts. Here it is important for the person to stop wasting energy, and to rest and sleep more. THIS IS A CRUCIAL PHASE, and if the person resorts to stimulants of any kind, he will abort and defeat the regenerative intent of the body. It is important that he have patience and faith and just wait it out, and after awhile he will get increasing strength which will exceed by far what he felt before he began the new program. Success in recovery or improvement of health hinges upon the correct understanding of this point--REALIZING that the body is using its main energies in more important internal work and NOT wasting it in external work involving muscle movements. Be wise--take it easy here and relax. Just coast in your work and social obligations until you are out of the woods.

As one continues on the improved diet and gradually raises the food quality, interesting symptoms begin to appear. The body begins a process called "retracing". The cellular intelligence reasons something like this: "Oh! Look at all those fine materials coming in. How wonderful--now we have a chance to get rid of this old garbage and build a beautiful new house. Let's get started immediately. Let's get this excess bile out of the liver and gallbladder and send it to the intestines for elimination. Let's get this sludge moving out of the arteries, veins and capillaries. These smelly, gassy, brain-stupefying masses have been here too long--out with them! These arthritic deposits in the joints need cleaning up. Let's get these irritating food preservatives, aspirins, sleeping pills and drugs out of the way along with these other masses of fat which have made life so burdensome for us for so long. Let's get going and keep going till the job is done--till we have a beautiful house--and from then on we'll keep it beautiful.

During the first phase (called catabolism), the accent is on elimination, or breaking down of tissue. The body begins to clean house--in short, to remove the garbage deposited in all the tissues--everywhere. During this period, the body "removes the ashes from the furnace preparatory to getting a better fire." Here the accentuation is on removal of the gross and immediate body obstructions. Wastes are discarded more rapidly than new tissue is made from the new food. This becomes evident as weight loss. This persists for a while and is then followed by the second phase--stabilization.

Here, the weight remains more or less stable. During this phase, the amount of waste material being discarded daily is equal to the amount of tissue which is being formed and replaced by the newer, more vital food. This occurs after the excess of obstructing material in the tissues has been removed. This stage persists for awhile and is then followed by a third phase--a build-up period (called anabolism), wherein weight starts to go up, even though the diet is lower in calories than it was before. At this point, much or more of the interfering wastes have already been discarded--the tissues which have been formed since the diet was raised in quality are more durable and do not break down easily. Also, new tissues are now being formed faster. This is due to the improved assimilation made possible by the ceasing of wrong food-combining. The body's need for the usual amounts of food decreases, and we are able to maintain our weight and increased energies with less food. Many are able to function very efficiently on two meals a day and eventually even on one meal a day. As the body progressively increases in efficiency and decreases in tissue breakdown uhder exercise, so do we gradually need less and less food to maintain life. The higher the percentage of raw food one lives on, the slower the rate of tissue deterioration which one evolves into. A sick body requires a gradual, carefully worked-out entry into this stage, where one is able to live on a 100% unfired (raw) diet.

Returning to the symptoms which occur on a superior nutritional program--people who have had tendencies in the past to recurring skin rashes or eruptions will frequently tend to eliminate poisons and harmful drugs through the skin with new rashes or eruptions. If they go to a doctor now who is not familiar with this aspect of nutrition, he will diagnose it as an allergy. They ask, "How come: I'm eating better now than I ever did before, and instead I'm getting worse?" They don't understand that the body is "retracing." The skin is getting more alive and active. It's throwing out more poisons more rapidly now that the body is building more power which is saved from those hard-to-digest meals which have been discontinued. These toxins being discarded are saving you from more serious disease which will result if you keep them in your body too much longer--possibly hepatitis, kidney disorders, bllod disease, heart disease, arthritis, nerve degenerations or even cancer--depending upon your hereditary or structural weaknesses. Be happy you are paying your bills now in an easy-payment plan.

With some, colds which haven't appeared for a long time may occur, or even fevers. THIS IS NATURE'S WAY OF HOUSECLEANING. Understand that these actions are constructive, even though unpleasant at the moment. DON'T--but DON'T try to stop these symptoms by the use of certain drugs, or even massive doses of vitamins which will act as drugs in huge concentrations. These symptoms are part of a curing process, and don't try to cure a cure. These are NOT deficiency conditions or allergic manifestations--NOT if you are eating properly in quality, quantity, combination and sequence. Here is where experienced advice is a great value. Unfortunately, there are few books present today which give full guidance to the average reader. Try to find guidance through a doctor or teacher who has the requisite experience in this most confusing of all subjects--nutrition in relation to health and disease.

You may be eating perfectly in regard to quantity, quality, and observing all the correct rules, and still symptoms will occur. Those who have lived better lives in the past--who have eaten better foods and who have abused their bodies less with over-eating will have reactions ranging from almost none at all or very mild to symptoms which may be uncomfortable or acute. Those who have lived worse lives and poisoned themselves more will experience more severe symptoms if their liver, kidneys, or other important eliminating organs have been damaged. When they hava been renovated to the point of fair working order, they will no longer produce symptoms.

Headaches may occur at the beginning; fever and/or colds also may appear; the skin may break out; there may be a short interval of bowel sluggishness, occasional diarrhea, feelings of tiredness and weakness, disinclination to exercise, nervousness, irritability, negativity or mental depression, frequent urinations, etc.,etc. However, the great majority of people find their reactions tolerable and are encouraged to bear with them because of the many improvements which have already occurred and are becoming more evident with each day. This acts as an inspirational force to them.

The symptoms will vary according to the materials being discarded, the condition of the organs involved in the elimination, and the amount of energy you have available. The more you rest and sleep when symptoms are present, the milder they are and the more quickly they are terminated. Be happy you are having symptoms. REALIZE DEEPLY that your body is becoming younger and healthier every day because you are throwing off more and more waste which would eventually have brought pain, disease and much suffering. Those who have the worst symptom-reactions and follow through to their successful termination are thus avoiding some of the worst diseases which would eventually have developed had they continued their careless eating habits.

Don't expect to go on an ascending scale of quality--that improving your diet will make you feel better and better each day until you reach perfection. The body is cyclical in nature, and health returns in a series of gradually-diminishing cycles. For example --you start a better diet and for awhile you feel much better. After some time, a symptom occurs--you may feel nauseous for a day and have diarrhea with a foul-smelling stool. After a day, you feel even better than before and all goes fine for awhile. Than you suddently develop a cold, feel chills and lose your appetite. After about two months, when you suddenly develop an itch or rash. You still don't take anything special for it. This rash flares up, gets worse and continues for ten days, and suddenly subsides. Immediately after this your energy has increased more than ever before. The rash became an outlet for the poisons in the liver. This is how recovery occurs--like the cycles in the Dow-Jones Average at the beginning of a bull market recovery. You feel better, a reaction occurs and you don't feel as well for a short while. You recover and go higher for awhile. Then another reaction occurs--milder than the last. You recover and go even higher. And so it goes--each reaction milder than the last as the body become purer, each becoming shorter in duration and being followed by a longer and longer period of feeling better than ever before, until you reach a level plateau of vibrant health. Here you become relatively disease-free and are filled with ever-increasing joy, life and the happiness which comes from sheer well-being. The first laws we must learn to obey are the laws of Nature. We must learn to eat simple, pure and natural foods, properly prepared and combined, and our bodies in return will cast off all the evil we have taken in during our lives. All repentance must begin here in the body--trhough pure diet and natural foods. Then, just have faith, sit back and watch what happens. Before your own eyes, you will daily see signs that will cause you to wonder at this vast intelligence in operation that staggers the comprehension Let us give ourselves a chance to experience what it means to be really healthy and fully alive--to feel the joy of living by aligning ourselves to God's (Nature's) laws as intended for man--through the eating of natural (normal) foods. This indeed is the prime prerequisite in man's physical, mental and spiritual unfoldment.

SCIENTIFIC STUDIES ON MARINE LIPID COMPLEX (DETAILED INFORMATION ON HERBAL LIFELINE)

The #1 killer in America is Heart Disease. According to the American Lung Association, in 1981 there were 160 heart attacks every minute in the United States.

Herbal Lifeline was formulated by Dr. Richard Marconi, one of the leading nutritionalists for the past 22 years, and Dr. George Pigott, a senior professor at the University of Washington. Dr. Pigott has 35 years experience in the Food Sciences Division, especially marine lipid complex. Dr. Pigott feels that nutrition, not drugs, is the solution to the long-term remedy of all the heart disease in this country.

Herbal Lifeline has been found to reduce triglycerides, lower blood pressure, eliminate or reduce cholesterol and cleanse the plaque out of the arteries; thereby reducing the possibility of heart disease without the side effects of drugs.

Herbal Lifeline contains Marine Lipid Complex, Octacosanol (an extract from wheat germ oil to increase energy), Selenium (a trace mineral added as a result of studies done in America and on 12,000 children in China with a history of congestive heart failure), and Vitamin E (which can enlarge arteries permitting better circulation and prevents the formation and deposition of a certain harmful form of fatty substances). These ingredients are in a base of Wheat Germ Oil and Leonuris C., Hawthorn Berry and Butterbur (three herbs that have a long history of positive effects on the cardiovascular system).

There have been two studies that have shown how the Marine Lipid Complex could be vitally important to our health. One study was done by Dr. Avery Nelson in Seattle, Washington. Dr. Nelson put 126 people on a standard diet and and 80 people on a high fish diet. The people remained on the diets for 16-19 years. The people on the high fish diet ate fish seven days a week. All the people had already had one or more heart attacks when Dr. Nelson put them on the diets. The people on the standard diet had an 8% survival rate compared to a 36% survival rate of the people on the high fish diet. Of the people between the ages of 56-70, those on the standard diet had a survival rate of 5% compared to a 32% survival rate with the people on the high fish diet. Dr. Nelson's article was published in 1970.

Another study conducted four years ago by Dr. Jay Divert of Denmark compared the Greenland Eskimo to the people of Denmark and the United States. During a two-year study, only 5.3% of the Greenland Eskimos died from Heart Disease, while 34.7% of the Danish and 40.4% of the Americans died from Heart Disease. The only noticeable difference between the people of the three countries was that the Greenland Eskimo is on a tremendously high fish diet. The previous ten years before the study there was no record of a Greenland Eskimo dying of a heart attack. The Greenland Eskimos that moved to Denmark had the same death rate as the Danish.

The results of these studies can be scientifically explained. We have two kinds of essential fatty acids in our blood stream, Omega-3 and Omega-6 fatty acids. The Omega-6 fatty acids are found in the foods you normally eat, vegetable oil and most of the unsaturated fats you consume. The Omega-3 fatty acids are found in marine animals, as a result of eating the food chain in the ocean.

The Greenland Eskimo has a higher ratio of Omega-3 fatty acids than Americans do because of their high fish diet. By increasing the ratio of Omega-3 fatty acids to Omega-6 fatty acids we can eliminate many of the problems with the heart. The ratio of Omega-3 fatty acids to Omega-6 fatty acids is almost one to one in the Greenland Eskimo. The ratio of of Omega-3 fatty acids found in Americans is considerably lower than Omega-6.

The difference between the two fatty acids is that the Omega-3 fatty acids can carry cholesterol, so it does not solidify or aggregate in the arteries and deposit. The Omega-6 fatty acids can solidify and deposit in the arteries and are corrollated with many problems.

For these reasons, Herbal Lifeline is particularly high in Omega-3 fatty acids. The Company has combined this unique complex with several important nutritional factors and a carefully selected blend of herbs to enhance the value of this very special nutritional supplement to be used by people with heart problems or as a preventative to reduce the chance of heart disease.

4. TROUBLESHOOTING

A. IMPROPER DIGESTION - USE ALOE JUICE 2-4 OZ. 3 TIMES A DAY BEFORE MEALS.

B. MEDICATIONS (HIGH BLOOD PRESSURE, HORMONES OR BIRTH CONTROL PILLS) CAN SLOW DOWN WEIGHT LOSS. HORMONES AND BIRTH CONTROL PILLS CAUSE A BUILD-UP OF EXCESS FLUID (MUST USE CELL-U-LOSS); HIGH BLOOD PRESSURE - ALREADY TAKING DIURETIC SO FLUID LOSS IS LESS. (GENERALLY LOSE WEIGHT SLOWER)

C. DIET POP IS VERY HIGH IN SODIUM (SALT). CAN CAUSE RETENTION OF FLUIDS.

D. SOFT WATER CAUSES SAME PROBLEM AS DIET POP.

E. CHECK HOW MUCH PROTEIN POWDER IS BEING USED AND IN WHAT LIQUID (REMEMBER, THEY MUST USE LEVEL TABLESPOONS).

F. CAFFEINE WILL RETARD LECITHINS ABILITY TO BREAK UP FAT CELLS.

G. DRINK EIGHT - 8 OZ. GLASSES OF WATER A DAY. CANNOT USE COFFEE OR TEA AS A PART OF THAT-IT MUST BE WATER.

H. CONSTIPATION PROBLEMS AND OTHER DIGESTIVE PROBLEMS CAN BE AVERTED IF CUSTOMER BEGINS PROGRAM USING ALOE JUICE.

I. NAUSEA, HEADACHES, LIGHT HEADEDNESS, SKIN BREAKOUTS, ARE SIGNS OF DETOXIFICATION AND WILL CLEAR UP WITHIN 7-10 DAYS. REFER TO "WHAT SYMPTOMS TO EXPECT WHEN YOU IMPROVE YOUR DIET" BY DR. STANLEY BASS.

J. SOME HEAVY SMOKERS HAVE STRONG DETOXIFICATION SYMPTOMS (VOMITING).

K. NAUSEA WITHIN ½ HOUR AFTER EATING CAN BE A RESULT OF THE VEGETABLE PROTEIN COATING ON THE TABLETS. TO AVOID, DRINK A SMALL AMOUNT OF SHAKE OR EAT A FEW BITES FROM BULK MEAL BEFORE TAKING TABLETS.

L. SOMETIMES PUTTING PEOPLE ON THE SHAKES MIXED IN MILK CAUSES CONSTIPATION IF THEY DO NOT NORMALLY DRINK MILK. ENCOURAGE THEM TO TRY THE SHAKES MIXED WITH FRUIT JUICES.

M. THREE WAYS TO GET OFF A PLATEAU:

1. TAKE TWICE AS MUCH ALOE JUICE AS YOU HAVE BEEN TAKING.
2. TAKE 3 SHAKES FOR ONE DAY ONLY AND EAT NO BULK MEAL.
3. EAT ONLY CARBOHYDRATES FOR ONE DAY ONLY AND THEN GO BACK TO REGULAR PROGRAM.

*BE SURE TO USE CORRECT PRODUCT NAMES WHEN SELLING THE PRODUCTS.

CARBOHYDRATES: YOUR BODY'S PRIMARY FUEL.

Carbohydrates are the primary energy source for all body functions and muscular exertion, and are necessary to assist in the digestion and assimilation of other goods. They provide the body with immediately available calories for energy by producing heat in the body when carbon in the system combines with oxygen in the bloodstream. Carbohydrates also assist in the regulation of protein and fat metabolism: fats require carbohydrates for their breakdown in the liver.

Starches, sugars and cellulose are the principal carbohydrates. From the starches or polysaccharides; which are chains of simple sugars, come the body's most efficient fuel. Starches such as grains, legumes and vegetables, for instance, are easily digested and converted to glucose, which is then carried by the blood to all cells of the body. Whole grains and legumes also offer the advantage of supplying the B vitamins your body needs in order to burn glucose as fuel.

FATS: YOUR CONCENTRATED ENERGY SOURCE.

Fats make up another class of compounds that serve mainly as an energy source. Fats must be "emulsified" before they can be absorbed by the body because in contrast to the digestive system, which is primarily water based, fats are not water soluble. Emulsification is essentially a process by which fatty materials are made water dispersible by combining with the bile acids which act as emulsifying agents. In addition of being a concentrated source of energy, fats serve certain structural functions, such as being a part of all cell membranes and providing insulation and protection for all internal organs.

Basically, food supplies two types of fat, both of which are important to good health; saturated and unsaturated. These are classified according to the hydrogen atom content of their fatty acid chains. Saturated fatty acids are those that are usually solid at room temperature and which,except for coconut oils, are derived primarily from animal sources: meat, butter, milk products and egg yolk. Unsaturated fatty acids, which include polyunsaturates, are generally cholesterol free and are usually liquid at room temerature. They come from a variety of sources: vegetable, vegetable oils, margarines and nuts.

There are three fatty acids which are commonly designated as "essential": linoleic, arachidonic and linolenic. These unsaturated fatty acids are important for the health of the blood, arteries and nerves, and are also necessary for normal growth. Pure, natural vegetable oils---safflower, sunflower, soybean, wheat germ and cottonseed--- are the best sources.

Cholesterol is a fatlike substance which is found in every body cell. Part of the cholesterol in our body comes from food, but even more of it is manufactured by the body. Since cholesterol is found only in animal fats and not in vegetable fats, food choices can affect the cholesterol level in your body.

PROTEINS: THE BODY BUILDERS

Proteins are one of the most important elements for the maintenance of good health and the growth and rebuilding of all body tissues. They are also the major source of building material for muscles, blood, skin, hair and internal organs, including the heart and brain. Proteins are actually complex molecules made up of smaller structures called amino acids. The body requires approximately twenty two amino acids. Fourteen of these can be produced in the adult body: the eight that cannot be produced are called "essential" amino acids because they must be supplied in the diet.

When a food contains all the essential amino acids, it is a "complete protein": foods that are low in some of the essetial amino acids (or lack them totally) are called "incomplete proteins". Most meat and dairy products are complete protein foods, while the majority of fruits and vegetables are incomplete protein foods. However, some vegetable proteins are good sources of essential aminn acids and are high quality proteins. Examples are yeast, soybean protein and peanut protein (such as that obtained from peanut butter.

Although a single food may be a "low quality" protein source, when combined with another "low quality" protein, the result can be of very good value, since one complements the amino acid content of the other. An example is cereal combined with milk because it provides maximum effective use of the amino acids present in both. Other examples include macaroni and cheese, casserole dishes combined legumes with small amounts of meat, and sandwiches that combine cereal grains, vegetables and cheese.

VITAMINS: CATALYSTS TO GOOD HEALTH

Vitamins are a group of organic compounds that are necessary for the normal metabolism of other nutrients. They perform an important role as co-enzymes and they act as catalysts to facilitate the reactions that cause nutrients to be used for energy, building cells or maintaining cells and tissue.

Vitamins are either water-soluble or fat-soluble, characterized by the manner in which they are absorbed by the body. Most vitamins are water-soluble, which means they can be transported by the blood and absorbed by the cells where they are needed. The water-soluble vitamins such as Vitamin C and the B-Complex, cannot be stored by the body and any excess is eliminated in the urine. Therefore, the body's supply must be replenished on a regular daily basis.

In contrast to water-soluble vitamins, fat-soluble vitamins (like Vitamins A,D, and E) can be stored in your body. If your dietary intake of these nutrients is inadequate, then the need for these reserves becomes critical. One of the best known and most publicized fat-soluble vitamins is Vitamin E. However, there has been some confusion as to which forms are natural and which are synthetic. As a basic guideline, the natural form of Vitamin E is usually designated by the prefix "d-alpha."

In contrast to fats, carbohydrates and protein, a vitamin has no inherent energy or caloric value. Also, with a few exceptions, these vital organic compounds cannot be manufactured by the body; they must be supplied in the diet or through supplementation. Vitamins work as a team in your body, interacting with each other. To be effective they usually require the presence of another vitamin or nutrient. For example, Vitamin E and zinc protect Vitamin A for absorption and utilization in the body.

MINERALS: SIMPLE BUT VITAL NUTRIENTS

Minerals are inorganic and simple compounds that make up 4-5% of your total body weight. Minerals play a more important role in the body than their quanities might indicate. In combination with organic compounds, they are constituents of vitamins, hormones, and enzymes as well as cells and especially the hard tissues like bones and teeth.

The body requires approximately 17 essential minerals to contribute to vital bodily functions. Without minerals, vitamins cannot function in the body. Minerals are divided into two main groups; based on their quantity in the body. Macrominerals is the name for minerals that are required and present in the body in large amounts. Calcium is a good example since it is present in the body in greater amounts than any other single mineral element, and is vitally important to the health of teeth and bones.

Trace minerals (microminerals) such as zinc and iron, are also needed in the body, but in lesser amounts. Iron, the most abundant trace mineral is found in every tissue cell and is extremely valuable to the quality of the blood. Zinc is the second largest quantity trace mineral and is related to the normal absorption and action of vitamins especially the B-complex.

SAFE-SENSIBLE WEIGHT LOSS

+

GOOD NUTRITION

The Amazing Magic of Natural Herbs

TRAINING BOOKLET

Updated

This booklet is not official
literature, but merely a guide to be
used for informational purposes.

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KEYS TO SUCCESSFUL BUSINESS

1. USE ALL OF THE PRODUCTS PERSONALLY.
2. CARE MORE ABOUT YOUR CUSTOMER LOSING WEIGHT THAN THE MONEY YOU MAKE.
3. CARE MORE ABOUT YOUR DISTRIBUTORS AND THEIR PROFIT THAN YOU DO ABOUT YOUR OWN.

REFERENCE POINTS ON NUTRITION

1. 90% OF WHAT PEOPLE SAY IS OPINION.
2. 10% OF WHAT PEOPLE SAY IS FACT.
3. F.D.A. (FOOD AND DRUG ADMINISTRATION)
    - A. THEY DO NOT APPROVE PRODUCTS. THEY ONLY DISAPPROVE PRODUCTS.
    - B. THEY HAVE THREE LISTS:
        - 1) NO NO LIST - DISAPPROVED PRODUCTS.
        - 2) LIST OF INGREDIENTS NOT TESTED LONG ENOUGH.
        - 3) G.R.A.S. LIST (GENERALLY RECOGNIZED AS SAFE)

        ALL OF OUR PRODUCTS ARE ON THE G.R.A.S. LIST !
    - C. MEGA DOSAGE LAW

        WE MUST ABIDE BY-WARNING OR CAUTION STATEMENTS ARE REQUIRED ON THE LABEL IF ANY PRODUCT WILL BE HARMFUL TO ANY HEALTH PROBLEM OR ANY MEDICATION BEING TAKEN.
4. DON'T BUY THE STORIES PEOPLE FEED YOU. USING THE ABOVE REFERENCE POINTS, YOU HAVE THE ABILITY TO RESPOND IN A PROPER WAY.

    (ALSO, LEARN THE PAGE ON OVERCOMING OBJECTIONS)

* BIGGEST FEAR IN DIETING IS FAILURE ! (THIS IS COVERED IN FOLLOW-UP)

5. BODY NEEDS FOR GOOD HEALTH ON A DAILY BASIS:
    - A. PROTEIN - 40-60 GRAMS.
    - B. CARBOHYDRATES - 100 GRAMS
    - C. VITAMINS AND MINERALS
    - D. FATTY ACIDS - HELP METABOLIZE PROTEIN
    - E. ESSENTIAL OILS (ESPECIALLY UNSATURATED OILS)
6. HERBS CLEANSE THE ENTIRE SYSTEM (BLOOD AND DIGESTIVE) SO THAT THESE FIVE ESSENTIAL THINGS NEEDED FOR GOOD HEALTH CAN BE ABSORBED. WHEN THE BODY IS NOT FUNCTIONING PROPERLY, YOU CANNOT FIGHT DISEASE.
7. TOXINS ARE CHEMICAL INGESTED THROUGH THE FOOD WE EAT AND DRINK:
    - A. ADDITIVES
    - B. PRESERVATIVES
    - C. SPRAYS
    - D. CHEMICALS USED IN THE PROCESSING OF FOODS (IE. ORANGE JUICE, ETC.)

8. BODY GETS RID OF TOXINS THROUGH:

   A. BREATHING
   B. SKIN
   C. MOUTH
   D. ELIMINATION

9. ONE PERSON IN TWENTY WILL HAVE PROBLEMS WHEN THEY BEGIN ON THE PROGRAM BECAUSE THEIR BODIES ARE FULL OF TOXINS. THESE ARE THE COMMON SYMPTOMS WHEN THE BODY IS HAVING TROUBLE GETTING RID OF TOXINS:

   A. DIARRHEA
   B. CONSTIPATION
   C. HEADACHE
   D. NAUSEA
   E. BREAKOUTS

   * USE OF ALOE JUICE WILL DECREASE THESE PROBLEMS TO 1 IN 40.

   IF YOU DO NOT PUT UP WITH THE DISCOMFORT OF GETTING THE TOXINS OUT, YOU WILL HAVE DISEASE LATER.

   READ THE DR. STANLEY BASS LETTER

10. EVERY 120 DAYS YOUR BODY REPLACES CELLS. BODY IS MADE UP OF PROTEIN CELLS. YOU MUST HAVE PROTEIN TO SUSTAIN LIFE. THE BODY WILL EAT ITSELF TO STAY ALIVE. MANY DIETS ARE NOT BALANCED AND ACTUALLY DO MORE DAMAGE THAN GOOD BECAUSE THEY TAKE WEIGHT FROM VITAL ORGANS INSTEAD OF FROM THE FAT CELLS. THE BODY WILL EAT ITSELF TO STAY ALIVE.

11. PROTEIN IS MADE UP OF AMINO ACIDS. AMINO ACIDS IN DIFFERENT COMBINATIONS SUPPLY THE RIGHT PROTEIN TO EVERY CELL.

    22 AMINO ACIDS ARE NEEDED TO ACCOMPLISH THIS.

    14 AMINO ACIDS CAN BE PRODUCED NATURALLY IN THE BODY.

    8 AMINO ACIDS MUST BE GOTTEN FROM AN OUTSIDE SOURCE.

WHO CAN USE THESE PRODUCTS ? ALL PEOPLE WHO CAN EAT FOOD!!!

THESE PRODUCTS SUPPLY ALL THE NUTRIENTS YOU NEED IN BALANCE ON A DAILY BASIS. USING THE PROPER DOSAGES, BABIES, ELDERLY, PEOPLE WITH HEALTH PROBLEMS, ON MEDICATION, ETC. CAN USE THE PRODUCTS.

REMEMBER: THE PRODUCTS ARE JUST LOW CALORIE FOOD!

PRODUCT KNOWLEDGE

SLIM AND TRIM

FORMULA #1 - PROTEIN POWDER

1. PROVIDES 18 AMINO ACIDS, INCLUDING 8 ESSENTIAL AMINO ACIDS. THE OTHER 4 AMINO ACIDS WILL BE PRODUCED WITH THE 18 IN BALANCE.
2. HIGH QUALITY VEGETABLE PROTEIN.
3. CAUSES THE BODY TO BURN FAT.
4. MARK THE CONTAINER SO THAT THE CUSTOMER WILL REMOVE ¼ OF THE POWDER.

   WRITE THE WORDS SHAKE ON THE CAN, AND BE SURE THE CUSTOMER UNDERSTANDS THAT THEY SHOULD USE LEVEL TABLESPOONS!
5. 2 SHAKES PER DAY IN PLACE OF TWO MEALS ----- LOSE

   1 SHAKE PER DAY IN PLACE OF ONE MEAL ----- MAINTAIN

   3 SHAKES PER DAY WITH MEALS ----- GAIN
6. SHAKES WILL PROVIDE UP TO 200 CALORIES PER MEAL.

   2 T. SHAKEN POWDER = 70 CALORIES
   NON-FAT MILK = 95 CALORIES
   FRUIT = 35 CALORIES

   200 CALORIES

   NEED TO KEEP TOTAL CALORIE INTAKE AT 1,000 CALORIES PER DAY IN ORDER TO LOSE WEIGHT. IF YOU DO NOT LOSE ON 1,000 CALORIES, THERE IS A PROBLEM IN DIGESTION (BODY FUNCTION).
7. CHILDREN MAY USE THE POWDER (1 TABLESPOON PER 80 LBS. BODY WEIGHT).

   E.G. A 40 LB. CHILD WOULD USE ½ TBLSPN.

FORMULA #2 - HERB TABLETS

1. 14 HERBS THAT NATURALLY SUPPRESS THE APPETITE. CLEANSES BOTH THE BLOOD AND DIGESTIVE SYSTEM OF TOXINS.
2. WILL CLEANSE THE TOXINS THAT ARE NOT DIGESTED AND ARE STORED IN THE FATTY TISSUE.
3. 2 TABLETS 3 TIMES A DAY ------ LOSE
   2 TABLETS 3 TIMES A DAY ------ MAINTAIN
   3 TABLETS 2 TIMES A DAY AFTER 1ST AND 3RD MEAL ------ GAIN
4. IF HUNGRY BETWEEN MEALS, INCREASE TO 4 AT EACH MEAL.
5. CHILD'S DOSAGE: 60 LBS. AND OVER USE AS ADULT
   25-60 LBS. USE 1 TABLET THREE TIMES A DAY.

FORMULA #3 - VITAMINS AND MINERALS

1. FORMULA #3 HAS EVERY VITAMIN, MINERAL AND TRACE MINERALS THAT THE BODY LOSES EVERY DAY THROUGH NORMAL ELIMINATION.
2. MEGA DOSAGES ARE NOT NECESSARY (IF COLON IS CLEAR) FOR PROPER ABSORPTION.
3. TAKE 1 TABLET 3 TIMES PER DAY TO LOSE, MAINTAIN, OR GAIN.
4. VEGETABLE PROTEIN COATING HELPS YOU METABOLIZE THE PRODUCT.
5. CHILD'S DOSAGE: SAME AS ADULT FOR CHILD OVER 60 LBS.
   25-60 LBS. USE ½ TABLET 3 TIMES A DAY.

FORMULA #4 - OIL

1. OIL CAPSULE THAT HELPS TIGHTEN THE SKIN AS YOU ARE LOSING WEIGHT.
2. SUPPLIES ESSENTIAL FATTY ACIDS WHICH AID IN THE DIGESTION AND ASSIMILATION OF PROTEIN.
3. CARRIES OIL SOLUABLE VITAMINS (A,D,E, & K) THROUGH THE SYSTEM AND HELPS THE BODY TO USE THEM.
4. TAKE 1 CAPSULE 3 TIMES A DAY TO LOSE, MAINTAIN, OR GAIN.
5. CHILD'S DOSAGE: 1 CAPSULE THREE TIMES A DAY FOR WEIGHTS ABOVE 25 LBS.

ALOE JUICE

1. AIDS IN DIGESTION AND ACCELERATES WEIGHT LOSS.
2. FINEST CLEANSER AND HEALER OF DIGESTIVE TRACT.
3. A LIVE PRODUCT, 92% FREE-FLOWING ENZYMES. NO WATER ADDED OR THICKENING AGENTS ADDED. THE LEAVES OF THE ALOE VERA PLANT ARE HAND-FILLETED TO PREVENT BITTERNESS. ONLY THE INSIDE OF THE PLANT IS USED. IT HAS BEEN STABLIZED WITH HERBS AND CONTAINS NO PRESERVATIVES, NATURAL OR OTHERWISE.
4. BECAUSE IT IS LIVE, IT HAS A 30-DAY SHELF LIFE WHEN OPENED. 6 MONTH SHELF WHEN SEALED.
5. DO NOT EXPOSE TO EXCESSIVE HEAT (BE CAUTIOUS OF LEAVING IN YOUR CAR DURING THE SUMMER)
6. WHEN YOU ARE HAVING A PROBLEM WITH NOT LOSING AND ARE CONSUMING ONLY 1,000 CALORIES A DAY, YOUR BODY IS NOT FUNCTIONING PROPERLY IN THE AREA OF FOOD DIGESTION AND ASSIMILATION. HERBAL ALOE WILL HELP AID THE DIGESTION AND ASSIMILATION BECAUSE IT CLEANSES YOUR SYSTEM.
7. DRINK 2-4 OZ. BEFORE YOUR BULK MEAL.
8. PEOPLE WITH PROBLEMS: 2-4 OZ BEFORE EACH MEAL (MINIMUM).
9. MAKES EVERYTHING IN THE SLIM AND TRIM PROGRAM WORK FASTER.
10. DRINK AS MUCH AS YOU CAN AFFORD!
11. DUE TO VARYING SOILS AND CLIMATIC CONDITIONS, ALOE VERA MAY OCCASIONALLY VARY SOMEWHAT IN FLAVOR. THE TASTE DIFFERENCE IN NO WAY AFFECTS THE QUALITY OF THE PRODUCT. THE PROPERTIES, INGREDIENTS, AND PERCENTAGES ARE ALWAYS CONSTANT. "IT'S LIKE TOMATOES, NO TWO EVER TASTE THE SAME".

NATURAL RAW GUARANA

1. GUARANA NATURALLY INCREASES ENERGY, MENTAL ALERTNESS, AND PROVIDES A NATURAL LIFT.

2. NORMALIZES ADRENAL GLANDS AND BRINGS ADRENAL FLOW UP OR DOWN AND STABILIZES IT IN THE BLOOD STREAM. CAFFEINE IS A CHEMICAL STIMULANT THAT CAUSES STRESS IN OUR CENTRAL NERVOUS SYSTEM AND CAN CAUSE OTHER SERIOUS PROBLEMS IN OUR BODY. N.R.G. WORKS IN THE ADRENAL SYSTEM WHERE NATURAL ENERGY IS PRODUCED.

3. CAN BE EFFECTIVE IN SOME TYPES OF ALLERGIES AND ASTHMA WHERE THE BODY PRODUCES EXCESSIVE HISTAMINES. SLUGGISH ADRENALS CANNOT ABSORB THESE HISTAMINES ADEQUATELY SO ANTIHISTAMINE DRUGS ARE USED TO REGULATE THE PROBLEM.

CELLULITE PRODUCT

1. CELLULITE IS CAUSED FROM A COMBINATION OF FLUID TRAPPED IN FAT CELLS AND POOR CIRCULATION (THE LESS CIRCULATION, THE HARDER THE FAT CELL BECOMES.) TOXINS ARE STORED IN FATTY TISSUE CAUSING A BUILD UP OF FLUIDS.

2. CELLULITE SHOWS MORE ON WOMEN BECAUSE THEIR OUTER THREE LAYERS OF SKIN ARE THINNER THAN MEN'S.

3. OXYGEN HELPS TO BREAK UP FAT CELLS.

4. INCREASES CIRCULATION PROVIDING ADEQUATE OXYGEN. THIS PRODUCT IS GOOD FOR SOMEONE WITH GENERALLY BAD CIRCULATION (COLD HANDS AND FEET).

5. CONTAINS 6 HERBS THAT HAVE A DIRUETIC EFFECT ON THE CELLS SO IT ELIMINATES EXCESS FLUIDS AND PROVIDES YOU WITH INCH LOSS.

6. 3 TABLETS PER DAY RECOMMENDED. MAXIMUM OF 4 BECAUSE OF LARGE POTASSIUM CONTENT AND POTASSIUM IS NOT WATER SOLUABLE.

7. COMPLETE SMOOTHING OF CELLULITE NORMALLY TAKES ABOUT 5-6 MONTHS.

SOUPS - BEEF FRENCH ONION CHICKEN

1. 80 CALORIES PER SERVING.

2. SODIUM (SALT) FREE- MUST BE SEASONED TO TASTE.

3. CAN BE USED FOR GRAVIES AND DIPS. TRY THE CHICKEN SOUP AS A COATING ON CHICKEN.

4. CONTAINS 7 HERBS FOR GOOD HEALTH.

5. A UNIVERSITY STUDY HAS SHOWN THAT SOUP, RATHER THAN SALAD, BEFORE A MEAL CAN AID IN WEIGHT LOSS.

TANG KUEI - (PRONOUNCED DON QUAI)

1. HERB FROM CHINA, AGED 7 YEARS TO PRODUCE EFFECTIVENESS.
2. RELIEVES MENSTRUAL DISORDERS
   - A. EFFECTIVE FOR MENOPAUSE
   - B. RELAXES AND STRENGTHENS INTERNAL ORGANS AND MUSCLES. GREAT FOR ATHLETES, ANYONE WHO EXERCISES, PROBLEMS CAUSED FROM TENSION.
3. OB/GYN DOCTORS RECOGNIZE AND USE THIS HERB AS AN EFFECTIVE TREATMENT FOR FEMALE PROBLEMS.
4. PROVIDES RELIEF FOR MIGRAINE HEADACHES. TAKE THREE TABLETS WITH SOME HERBAL ALOE FOR BEST RESULTS.
5. FOR MENSTRUAL CRAMPING:

   9 TABLETS THE FIRST DAY (3- THREE TIMES A DAY)
   7 TABLETS THE SECOND DAY
   5 TABLETS THE THIRD DAY
   3 TABLETS THE FOURTH DAY

   TAKE ONE OR TWO DAILY THROUGHOUT THE MONTH. THE SECOND MONTH, START WITH 7 TABLETS THE FIRST DAY. THIS IS NECESSARY TO DISCOVER WHAT AMOUNT WILL GIVE BEST RESULTS.
6. TANG KUEI CANNOT BE TAKEN WITH VITAMIN C. VITAMIN C DESTROYS THE ACTIVITY OF THE HERB. TAKE 2 HOURS BEFORE OR AFTER VITAMIN C. DO NOT USE A TIME-RELEASED VITAMIN C WHEN TAKING TANG KUEI.
7. FOR MENOPAUSE, TAKE 2-4 TABLETS ALONG WITH 4-6 OZ. OF HERBAL ALOE.
8. WORKS FASTER IF YOUR TAKE SOME ALOE JUICE WITH TANG KUEI.
9. SLEEP AID AND MUSCLE RELAXANT. TAKE 2-3 TABLETS WITH HERBAL ALOE BEFORE BEDTIME.

SKIN CARE PROGRAM

HERBAL FORMULATION (NOT JUST FRAGRANCED) SO YOU GET HEALTHY, HEALING EFFECTS. ALOE IS THE BASE FOR THE SKIN CARE PROGRAM.

FORMULA #1 - CLEANSER

1. REMOVES BOTH WATER SOLUABLE WASTES FROM SURFACE OF FACE AND OILY SUBSTANCES FROM THE SKIN (INCLUDING THE PORES).
2. THE DIRT THAT ACCUMULATES ON YOUR FACE (WASTES AND OILS) CAUSES LARGE PORES AND BLEMISHES ON YOUR SKIN.
3. EXCELLENT LUBRICANT FOR SHAVING.
4. REMOVE THE CLEANSER WITH A WARM, WET WASHCLOTH.

FORMULA #2 - SCRUB

1. MADE FROM GROUND CORN COB MEAL. SO MILD IT CAN BE USED DAILY ON MOST SKIN TYPES. DRY, SENSITIVE SKIN MAY ONLY REQUIRE TWICE A WEEK.
2. USE IT IMMEDIATELY AFTER CLEANSING.
3. REMOVES DEAD SKIN CELLS, STIMULATES NEW CELL GROWTH, PROVIDING A NATURAL SHEEN AND SMOOTH TEXTURE TO THE SKIN.
4. MASSAGE SCRUB ON FACE AND NECK FOR 2-3 MINUTES.
5. INCREASES CIRCULATION IN THE SKIN.
6. REMOVE WITH WARM, WET WASHCLOTH.

FORMULA #3 - TONER AND BALANCER

1. STIMULATES AND BALANCES SKIN BACK TO A NORMAL PH LEVEL.
2. REMOVES EXCESS RESIDUE AND SOOTHES SKIN.

FORMULA #4 - DAYTIME MOISTURIZER

1. BASED WITH COLLAGEN PROTEIN, WHICH WITH THE AID OF HERBS, PENETRATES THREE LAYERS OF SKIN.
2. HEALS, PROTECTS, SOFTENS, AND MOISTURIZES THE SKIN.
3. PROTECTS SKIN FROM THE HARSH ELEMENTS. FACE IS ONLY PART OF OUR BODY THAT HAS CONTINUAL EXPOSURE BOTH SUMMER AND WINTER TO THESE DAMAGING ELEMENTS.

REJUVENATING CREME

1. RESTORES ELASTICITY TO THE SKIN.
2. DIMINISHES WRINKLES, SOFTENS AND PROTECTS THE SKIN.
3. BASED WITH COLLAGEN AND ELASTIN PROTEIN.
4. GREATEST NEED FOR MOISTURE, ELASTIN AND COLLAGEN IS AT NIGHT WHEN THE NUTRIENTS ARE IN SHORTER SUPPLY BECAUSE OF A SLOW DOWN IN THE BLOOD SYSTEM WHICH SUPPLIES THEM.
5. HERBS HELP PROTEIN TO PENETRATE 7 LAYERS OF SKIN.
6. COLLAGEN PROTEIN PRESENT TO SMOOTH OUT UNDESIRABLE WRINKLES AND DIMINISH PREMATURE AGING.
7. CLEANSE FACE, USE TONER/BALANCER, THEN APPLY REJUVENATING CREME.

HERBAL SHAMPOO AND RINSE

1. HERBAL FORMULATED (NOT FRAGRANCED), TO BRING HEALTHY BENEFITS OF HERBS TO YOUR HAIR AND SCALP.
2. BRINGS OUT NATURAL COLOR AND HIGHLIGHTS, AND IS HELPFUL IN HEALING MANY SCALP PROBLEMS.

ALOE GEL

GOOD FOR ANY TYPE OF SKIN IRRITATION SUCH AS INSECT BITES, SCRAPES, BURNS, CUTS AND ABRASIONS.

ARTHRITIC PAIN RELIEVER

TEMPORARILY RELIEVES THE PAIN FROM ARTHRITIS, SOOTHES AND RELIEVES INFLAMMATION. CAN BE HEALING TO WOUNDS.

CARDIOVASCULAR PRODUCT

DESIGNED TO SUPPLY MANY OF THE NUTRITIONAL FACTORS ESSENTIAL FOR ACHIEVING AND MAINTAINING A HEALTHY CARDIOVASCULAR SYSTEM.

PUBLISHED SCIENTIFIC STUDIES THROUGHOUT THE WORLD INDICATE THAT THE NUTRIENTS IN THIS PRODUCT HAVE AIDED IN:

1. NORMALIZING BLOOD PRESSURE AND REDUCING PLASMA CHOLESTEROL.
2. LOWERING TRIGLYCERIDES.
3. ALLEVIATING THE ABNORMAL BUILD-UP OF PLAQUE IN THE ARTERIES.
4. PROVIDING NUTRITION FOR THE PROTECTION OF THE ENTIRE VASCULAR SYSTEM.
5. DOSAGE: 9 TABLETS PER DAY FOR PEOPLE WITH HEART DISEASE.
   3 TABLETS PER DAY FOR PREVENTATIVE USE.

HERBAL CHILDREN'S MULTI-VITAMIN

AN HERBAL MULTI-VITAMIN FORMULA FOR INFANTS AND CHILDREN. IT IS THE ONLY MICELLIZED MULTI-VITAMIN FORMULA WITH HERBS FOR CHILDREN IN THE WORLD. THROUGH THIS PROCESS OF MICELLIZATION, FAT SOLUABLE VITAMINS ARE TURNED TO A CONDITION SIMILAR TO WATER SOLUABLE VITAMINS; THEREFORE, VITAMINS A, D, & E ARE MORE EFFECTIVELY ABSORBED INTO THE BODY OF AN INFANT OR CHILD.

A PLEASANT-TASTING LIQUID WITH NO ARTIFICIAL FLAVORS OR COLORS.

FIBER PRODUCT

THIS HIGH-QUALITY ACIDOPHILUS AND DIETARY FIBER PRODUCT IS DESIGNED TO:

1. HELP RECONSTITUTE AND MAINTAIN ESSENTIAL FLORA OF THE GASTRO-INTESTINAL TRACT.
2. PROVIDE NUTRITION FOR A NATURAL CLEANSING OR SCRUBBING EFFECT ON THE INTESTINAL TRACT.
3. HELP CONTRIBUTE TO A WELL-BALANCED DIET.

DOSAGE: TWO TABLETS THREE TIMES A DAY.

MOOD BALANCER

THIS IS A NATURAL HERBAL FORMULA WITH AMINO ACIDS DESIGNED TO HELP TO NUTRITIONALLY:

1. COMBAT STRESS INDUCED DEPRESSION.
2. OFFSET STRESS RELATED MOODINESS.
3. NORMALIZE THREE HORMONES IN THE BRAIN THAT HANDLE STRESS.

DOSAGE: 1 TABLET THREE TIMES A DAY.

NOTE: GENERIC NAMES ARE USED FOR THE PRODUCTS BECAUSE OF THE COMPANY'S POLICIES ON USE OF THE PROPER NAMES IN PRINTED MATERIALS.

SCIENTIFIC STUDIES ON MARINE LIPID COMPLEX (DETAILED INFORMATION ON HERBAL LIFELINE)

The #1 killer in America is Heart Disease. According to the American Lung Association, in 1981 there were 160 heart attacks every minute in the United States.

Herbal Lifeline was formulated by Dr. Richard Marconi, one of the leading nutritionalists for the past 22 years, and Dr. George Pigott, a senior professor at the University of Washington. Dr. Pigott has 35 years experience in the Food Sciences Division, especially marine lipid complex. Dr. Pigott feels that nutrition, not drugs, is the solution to the long-term remedy of all the heart disease in this country.

Herbal Lifeline has been found to reduce triglycerides, lower blood pressure, eliminate or reduce cholesterol and cleanse the plaque out of the arteries; thereby reducing the possibility of heart disease without the side effects of drugs.

Herbal Lifeline contains Marine Lipid Complex, Octacosanol (an extract from wheat germ oil to increase energy), Selenium (a trace mineral added as a result of studies done in America and on 12,000 children in China with a history of congestive heart failure), and Vitamin E (which can enlarge arteries permitting better circulation and prevents the formation and deposition of a certain harmful form of fatty substances). These ingredients are in a base of Wheat Germ Oil and Leonuris C., Hawthorn Berry and Butterbur (three herbs that have a long history of positive effects on the cardiovascular system).

There have been two studies that have shown how the Marine Lipid Complex could be vitally important to our health. One study was done by Dr. Avery Nelson in Seattle, Washington. Dr. Nelson put 126 people on a standard diet and and 80 people on a high fish diet. The people remained on the diets for 16-19 years. The people on the high fish diet ate fish seven days a week. All the people had already had one or more heart attacks when Dr. Nelson put them on the diets. The people on the standard diet had an 8% survival rate compared to a 36% survival rate of the people on the high fish diet. Of the people between the ages of 56-70, those on the standard diet had a survival rate of 5% compared to a 32% survival rate with the people on the high fish diet. Dr. Nelson's article was published in 1970.

Another study conducted four years ago by Dr. Jay Divert of Denmark compared the Greenland Eskimo to the people of Denmark and the United States. During a two-year study, only 5.3% of the Greenland Eskimos died from Heart Disease, while 34.7% of the Danish and 40.4% of the Americans died from Heart Disease. The only noticeable difference between the people of the three countries was that the Greenland Eskimo is on a tremendously high fish diet. The previous ten years before the study there was no record of a Greenland Eskimo dying of a heart attack. The Greenland Eskimos that moved to Denmark had the same death rate as the Danish.

The results of these studies can be scientifically explained. We have two kinds of essential fatty acids in our blood stream, Omega-3 and Omega-6 fatty acids. The Omega-6 fatty acids are found in the foods you normally eat, vegetable oil and most of the unsaturated fats you consume. The Omega-3 fatty acids are found in marine animals, as a result of eating the food chain in the ocean.

The Greenland Eskimo has a higher ratio of Omega-3 fatty acids than Americans do because of their high fish diet. By increasing the ratio of Omega-3 fatty acids to Omega-6 fatty acids we can eliminate many of the problems with the heart. The ratio of Omega-3 fatty acids to Omega-6 fatty acids is almost one to one in the Greenland Eskimo. The ratio of of Omega-3 fatty acids found in Americans is considerably lower than Omega-6.

The difference between the two fatty acids is that the Omega-3 fatty acids can carry cholesterol, so it does not solidify or aggregate in the arteries and deposit. The Omega-6 fatty acids can solidify and deposit in the arteries and are correllated with many problems.

For these reasons, Herbal Lifeline is particularly high in Omega-3 fatty acids. The Company has combined this unique complex with several important nutritional factors and a carefully selected blend of herbs to enhance the value of this very special nutritional supplement to be used by people with heart problems or as a preventative to reduce the chance of heart disease.

SCHIZANDRA

MUCH RESEARCH HAS BEEN DONE ON THE BIOLOGICAL FACTORS THAT CONTRIBUTE TO THE AGING PROCESS. UNTIL RECENTLY, THE BODILY DETERIORATION THAT COMES WITH AGE HAS BEEN ACCEPTED AS JUST THE INEVITABLE EFFECT OF THE PASSING OF TIME. NOW WE KNOW THAT THE AGING PROCESS IS LARGELY THE EFFECT OF CELLULAR BREAKDOWN. VARIOUS FACTORS CONTRIBUTE TO CELLULAR BREAKDOWN, BUT THERE ARE CERTAIN NUTRIENTS--KNOW GENERALLY AS ANTI-OXIDANTS--THAT COMBAT THE CAUSES OF THIS DETERIORATION.

SCHIZANDRA CONTAINS THESE ANTIOXIDANT NUTRIENTS, AND, OF COURSE, THE HERB SCHIZANDRA (SCHIZANDRA CHINENSIS).

DISCOVERED OVER 4,000 YEARS AGO, THIS HERB HAS BEEN CALLED AN "ADAPTOGEN" BECAUSE OF ITS ABILITY TO HELP THE BODY ADAPT TO ADVERSE CONDITIONS. THERE IS A UNIQUE HEALING SUBSTANCE FOUND IN IT'S BERRY-LIKE FRUIT THAT BUILDS AN OVERALL RESISTANCE TO UNHEALTHY INFLUENCES. RATHER THAN HEALING ONE SPECIFIC AREA OF THE BODY, SCHIZANDRA CREATES A "STATE OF NONSPECIFIC INCREASED RESISTANCE", A PHRASE COINED BY A RUSSIAN RESEARCHER, N.V. LAZAREV.

RESISTANCE TO STRESS AND DISEASE, INCREASED ENERGY AND MUSCULAR ACTIVITY, NOURISHMENT FOR VISCERA (INTESTINES), IMPROVED VISION, AND THE STIMULATION OF HEALING TO THE ENTIRE BODY ARE ALL BENEFITS ATTRIBUTED TO SCHIZANDRA.

AMERCIANS ARE ONLY BEGINNING TO LEARN ABOUT SCHIZANDRA, AS IT HAS ONLY RECENTLY BEEN MADE AVAILABLE TO THE GENERAL PUBLIC. THE CHINESE HAVE KNOWN OF IT'S ALMOST MAGICAL QUALITIES FOR THOUSANDS OF YEARS, AND THE RUSSIANS AND SWEDES HAVE BEEN USING IT FOR SEVERAL DECADES.

SCIENTIFIC DATA HAS BEEN MULTIPLYING DUE TO THE MANY POSITIVE EFFECTS OF SCHIZANDRA. IN 1969, IN THE TOWN OF CHRICHIK OF THE TASHKENT REGION OF THE USSR, AN INFLUENZA EPIDEMIC WAS RAGING. A TEST WAS CARRIED OUT ON 559 CHILDREN WHO WERE SPLIT INTO TWO GROUPS. ONE GROUP RECEIVED SCHIZANDRA; THE OTHER DID NOT. AFTER A PERIOD OF TIME, THE GROUP RECEIVING SCHIZANDRA WAS FOUND TO HAVE A GREATER RESISTANCE TO INFLUENZA THAN THE GROUP DEPRIVED OF THIS DYNAMIC NUTRIENT.

WE MAY FIND THAT THIS LEGENDARY ADAPTOGEN HOLDS THE KEY TO PRESERVING A LONGER MORE FRUITFUL LIFE. BECAUSE SCHIZANDRA IS RARE AND ONLY FOUND IN CERTAIN REMOTE AREAS (TIBET, CHINA AND RUSSIA), IT IS AVAILABLE IN THE UNITED STATES, BUT IN LIMITED QUANTITIES.

TWO TABLETS, ONE IN THE MORNING AND ONE IN THE EVENING IS THE RECOMMENDED DOSAGE.

"FOR A MORE DETAILED GUIDE THAT EXPLAINS THE DIFFERENT THEORIES ON AGING AND THE NUTRIENTS THAT COMBAT THEM SEND FOR DR. RICHARD MARCONI'S BOOKLET, "LET'S GROW YOUNGER". SCIENTIFIC NUTRITION PRESS
P.O. BOX 3572
SEAL BEACH, CA 90740

$1.95 EACH, PLUS 50¢ FOR SHIPPING ($1.00 FOR 2 OR MORE)

FOLLOW-UP

1. CUSTOMER'S ATTITUDE OF FAILURE

   A. MOST PEOPLE HAVE TRIED TO DIET IN PAST AND FAILED. IT IS HELPFUL TO FIND OUT WHERE WEAKNESSES ARE (JUNK FOOD, CHOCOLATE, BREAD, COMPULSIVE EATING, SWEETS, NERVOUSNESS, BOREDOM, DEPRESSION, ETC.)

   B. CONSULTANT IS A SOURCE OF STRENGTH AND ENCOURAGEMENT ESPECIALLY THE FIRST 2 WEEKS BECAUSE THIS IS ALWAYS THE MOST DIFFICULT TIME AND WHERE THE GREATEST NUMBER OF DIETERS FAIL.

   C. REMINDER: SET BACKS, STAND STILLS, ETC. ARE NOT FAILURES. THE ONLY TIME YOU FAIL IS WHEN YOU QUIT.

2. CALLING SCHEDULE

   A. FIRST DAY: "HOW DID IT TASTE?" ASK HOW THEY MIXED THEIR SHAKE (LET THEM TELL YOU! IT WILL LET YOU KNOW IF THEY ARE FOLLOWING THE INSTRUCTIONS CORRECTLY -- IE. SHAKING THE CAN, LEVEL TABLESPOONS, ETC.)

   B. FOURTH DAY - THIS IS THE FIRST DAY THEY WEIGH AFTER STARTING THE PROGRAM. ASK ABOUT WEIGHT AND INCH LOSS. IF THEY HAVEN'T MEASURED, ENCOURAGE THEM TO START. (INCH LOSS IS AS ENCOURAGING AS A WEIGHT LOSS AND SOMETIMES YOU WILL NOT HAVE A WEIGHT LOSS BUT WILL HAVE LOST INCHES. HOW WOULD THAT MAKE YOU FEEL? GREAT!)

   C. SEVENTH DAY - NEXT WEIGH DAY. ASK HOW THEY ARE FEELING AND IF THEY ARE HAVING ANY PARTICULAR DIFFICULTIES WITH DIETING (HUNGER, ETC.).

      PRAISE AND ENCOURAGEMENT ARE VERY IMPORTANT FOR A DIETER TO HEAR. IT ACTS AS A SUPPORT ESPECIALLY IN THE BEGINNING.

   D. CALL ONCE A WEEK AFTER THAT. AT THE END OF THE SECOND WEEK ASK FOR REFERRALS.

      "TELL ME, MARY, DO YOU HAVE SOMEONE YOU KNOW WHO WOULD LIKE TO LOSE SOME WEIGHT AND YOU WOULD LIKE TO SHARE THE PROGRAM WITH?"

   E. 30 DAYS

      "HAVE YOU NOTICED THAT YOU ARE FEELING BETTER? THE REASON YOU FEEL BETTER IS BECAUSE YOU ARE USING A GOOD NUTRITIONAL PRODUCT THAT SUPPLIES YOUR BODY EVERYTHING IT NEEDS ON A DAILY BASIS."

      (THIS KEEPS PEOPLE USING THE PRODUCT AFTER THEY LOSE THEIR WEIGHT)

3. CUSTOMER FILE CARD

   A. CHECK CAREER BOOK FOR EXAMPLES.

   B. DIVISION OF FILE

      1. FIRST WEEK DIETERS.
      2. MONDAY CALLS.
      3. TUESDAY CALLS.
      4. CONTACT MADE MONDAY, CONTACT MADE TUESDAY.

EXAMPLE: ONCE A CUSTOMER GOES ON A ONCE A WEEK CALLING SCHEDULE, PLACE THEM IN ONE OF THE DAYS YOU HAVE SET UP FOR CALLING CUSTOMERS. AS YOU REACH THEM, THEN PLACE CARD IN CONTACT MADE SECTION. AFTER YOU HAVE COMPLETED CALLING FOR THAT WEEK, PLACE CARDS BACK IN MONDAY OR TUESDAY CALLS.

4. TROUBLESHOOTING

A. IMPROPER DIGESTION - USE ALOE JUICE 2-4 OZ. 3 TIMES A DAY BEFORE MEALS.

B. MEDICATIONS (HIGH BLOOD PRESSURE, HORMONES OR BIRTH CONTROL PILLS) CAN SLOW DOWN WEIGHT LOSS. HORMONES AND BIRTH CONTROL PILLS CAUSE A BUILD-UP OF EXCESS FLUID (MUST USE CELL-U-LOSS). HIGH BLOOD PRESSURE - ALREADY TAKING DIURETIC SO FLUID LOSS IS LESS. (GENERALLY LOSE WEIGHT SLOWER)

C. DIET POP IS VERY HIGH IN SODIUM (SALT). CAN CAUSE RETENTION OF FLUIDS.

D. SOFT WATER CAUSES SAME PROBLEM AS DIET POP.

E. CHECK HOW MUCH PROTEIN POWDER IS BEING USED AND IN WHAT LIQUID (REMEMBER, THEY MUST USE LEVEL TABLESPOONS).

F. CAFFEINE WILL RETARD LECITHINS ABILITY TO BREAK UP FAT CELLS.

G. DRINK EIGHT - 8 OZ. GLASSES OF WATER A DAY. CANNOT USE COFFEE OR TEA AS A PART OF THAT-IT MUST BE WATER.

H. CONSTIPATION PROBLEMS AND OTHER DIGESTIVE PROBLEMS CAN BE AVERTED IF CUSTOMER BEGINS PROGRAM USING ALOE JUICE.

I. NAUSEA, HEADACHES, LIGHT HEADEDNESS, SKIN BREAKOUTS, ARE SIGNS OF DETOXIFICATION AND WILL CLEAR UP WITHIN 7-10 DAYS. REFER TO "WHAT SYMPTOMS TO EXPECT WHEN YOU IMPROVE YOUR DIET" BY DR. STANLEY BASS.

J. SOME HEAVY SMOKERS HAVE STRONG DETOXIFICATION SYMPTOMS (VOMITING).

K. NAUSEA WITHIN ½ HOUR AFTER EATING CAN BE A RESULT OF THE VEGETABLE PROTEIN COATING ON THE TABLETS. TO AVOID, DRINK A SMALL AMOUNT OF SHAKE OR EAT A FEW BITES FROM BULK MEAL BEFORE TAKING TABLETS.

L. SOMETIMES PUTTING PEOPLE ON THE SHAKES MIXED IN MILK CAUSES CONSTIPATION IF THEY DO NOT NORMALLY DRINK MILK. ENCOURAGE THEM TO TRY THE SHAKES MIXED WITH FRUIT JUICES.

M. THREE WAYS TO GET OFF A PLATEAU:

1. TAKE TWICE AS MUCH ALOE JUICE AS YOU HAVE BEEN TAKING.
2. TAKE 3 SHAKES FOR ONE DAY ONLY AND EAT NO BULK MEAL.
3. EAT ONLY CARBOHYDRATES FOR ONE DAY ONLY AND THEN GO BACK TO REGULAR PROGRAM.

*BE SURE TO USE CORRECT PRODUCT NAMES WHEN SELLING THE PRODUCTS.

PRODUCT PRESENTATION

HI, MY NAME IS ______________________________

(MAKE SMALL TALK FOR A FEW MINUTES -- BUT BE CAREFUL NOT TO LET IT GET OUT OF HAND.)

BY THE WAY ____(NAME)______, HOW MANY POUNDS WOULD YOU LIKE TO LOSE?
HAVE YOU TRIED ANY WEIGHT LOSS PROGRAMS BEFORE?
WHY DO YOU FEEL IT FAILED?
WITH OUR PROGRAM, YOU CAN LOSE BETWEEN 10-29 POUNDS IN A MONTH, AND NOT (ANSWER WHY THEY FAILED). WEIGHT LOSS IS A VERY INDIVIDUAL THING, AND THE AMOUNT OF WEIGHT YOU WILL LOSE WILL DEPEND A LOT ON YOU. A GOOD WEIGHT LOSS DOESN'T TAKE PLACE OVERNIGHT.

(BRING OUT THE SLIM AND TRIM PROGRAM) WE HAVE ENOUGH HERE FOR A 30-DAY SUPPLY OF MOST OF THE PRODUCTS. THIS IS A COMPLETELY BALANCED PROGRAM SO YOUR BODY GETS ALL THE NUTRIENTS IT NEEDS ON A DAILY BASIS. WHEN YOUR BODY IS GETTING ALL THE VITAL NUTRIENTS, IT WILL NOT CRAVE THINGS LIKE CHOCOLATE, SWEETS, CAFFEINE.

FORMULA #1 GIVES YOU ALL THE PROTEIN AND CARBOHYDRATES YOU NEED ON A DAILY BASIS. (GO THROUGH INSTRUCTIONS ON WHEN TO USE AND HOW TO MIX THE POWDER. WRITE ON THE CAN SHAKE, MAKE A MARK ¼ WAY DOWN, ETC.) (BE SURE TO PUT YOUR NAME AND PHONE NUMBER ON THE CAN!)

FORMULA #2 IS OUR MIRACLE WORKER. IT HAS 14 HERBS WHICH HELP CLEANSE THE SYSTEM AND HELP TO NATURALLY SUPPRESS YOUR APPETITE. YOU TAKE TWO OF THESE THREE TIMES A DAY. IF YOU HAVE HUNGER PAINS AT A PARTICULAR TIME YOU CAN TAKE ADDITIONAL ONES.

FORMULA #3 GIVES YOU ALL THE VITAMINS AND MINERALS YOU NEED ON A DAILY BASIS. YOU TAKE ONE OF THESE 3 TIMES A DAY.

FORMULA #4 KEEPS YOU FROM HAVING SAGGY, BAGGY SKIN.

ALOE JUICE MAKES EVERYTHING WORK FASTER. YOU NEED IT TO HELP YOU DIGEST YOUR FOOD PROPERLY AND CLEANSE YOUR SYSTEM.

GUARANA HELPS TAKE CARE OF THE SUGAR BLUES. IT NATURALLY INCREASES THE ENERGY LEVEL SO YOU DON'T FEEL TIRED. IT DOESN'T GIVE YOU A HIGH; IN FACT, FOR HYPERACTIVE CHILDREN IT WILL QUIET THEM DOWN.

THIS PRODUCT GETS RID OF CELLULITE. IN 3-4 WEEKS THERE WILL BE SOME SMOOTHING, BUT IT USUALLY TAKES 3-4 MONTHS TO GET RID OF IT COMPLETELY.

TIPS FROM YOUR HERBALIFE CONSULTANT

1. Shake the can of protein powder each time you measure or you will be getting more calories than you need. Remember to use level tablespoons.
2. Drink at least 8 glasses of water each day. This helps to flush out the excess fluid in our systems.
3. Remember to take your tablets 3 times a day -- once with each meal. If you forget, double up on them, but get in the recommended amount for each day.
4. If you have a problem with constipation, increase your water intake and take Herbal Aloe. (2-4 ounces before each meal -- with shakes and bulk meals)
5. Remember - the purpose of this program is to lose your weight and to establish a lifetime of good health and staying slim.
6. Call me if you have any questions or if you are finding yourself struggling with dieting. The first week or two of a diet is always the hardest. But with this program, you will be feeling so good within a week or two that you will be encouraged and the diet will seem much easier to stay on.
7. Take it one day at a time. The first week you need to write down everything you eat, including every morsel that you nibble on. This will help you to accurately evaluate your weight loss. Remember, this program will work for you if you follow it.
8. If you feel you need extra energy, try our N.R.G.
9. Try to increase your physical activity.

RECIPES (using blender)

Prefreeze milk in ice trays.

3-4 milk cubes
8 oz. milk (nonfat)
Protein Powder
  Add any of the following:
  Any fresh or frozen fruit
  ¼ of a banana, fresh or frozen
  ½ envelope of ALBA 77 chocolate
   (or strawberry flavor)

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2 Tbsp. each:
  frozen pineapple juice concentrate
  frozen orange juice concentrate
  nonfat dry milk
1 cup water
¼ banana, fresh or frozen (optional)
Protein Powder

8 oz. fruit juice (apple, cranapple, orange, etc.)
3-4 frozen strawberries (or other fruit)
¼ banana, fresh or frozen
Protein Powder

3 Tbsp. frozen orange juice concentrate
8 oz. water
2 Tbsp. nonfat dry milk
Protein Powder

PROTEIN POWDER CAN BE BLENDED OR STIRRED IN ANY FRUIT JUICE OR JUST PLAIN MILK.

IT'S GREAT IN YOGURT!

HINTS TO HELP YOU LOSE

1. Start off your bulk meal with hot soup. Preferably beef broth, chicken broth or consomme. It is a good appetite spoiler and in recent university studies has been proven a real aid in weight loss.

2. Save calories for the time of day when you most need them and they give you the most pleasure.

3. Shakes have 200 calories each. So in order for you to stay at 1000 calories per day, your bulk food should not exceed 600 calories, including any snacks.

4. Don't depend on food for most of your rewards. Make a point of scheduling other daily pleasures for yourself like a get-away-from-it-all swim or walk or a half hour reading time so you won't look to food as your only gratification.

THE INCREDIBLE 100-CALORIE CHART

100 calories can get you a lot of food --- or very little.

FOOD	MEASURE
asparagus	3½ cups
banana	1 medium
beef, lean ground	1 3/4 ounces
bean sprouts	3 cups
broccoli, fresh	2½ cups
bread, whole wheat	2 slices
canteloupe	1 small
chicken, white meat	2 ounces
cheese (swiss, cheddar)	1 ounce
eggs, whole large	1¼ egg
fish, filet of sole	4½ ounces
mushrooms	5 cups
orange juice, fresh	1 cup
peanut butter	1 tablespoon
potato, baked	1 small
popcorn, lightly salted	2½ cups
raspberries	1¼ cups
spinach, fresh	4½ cups
strawberries, frozen	2 cups
tomatoes	3 medium
zucchini	5 cups

5. Eat what you genuinely like---and avoid what you really detest. To be successful on a diet, you need to retain those flavors, textures and fragrances that you enjoy. The way to cut calories is simply to eat less of those favorites. Try the spaghetti as a side dish, served on a salad plate, in combination with clear soup and a green salad. If you have a realy sweet tooth, indulge---save your calorie allotment so you can enjoy a small piece of cake.

GOOD _____________, MAY I HELP YOU?
WHO AM I SPEAKING WITH PLEASE?
APPROXIMATELY HOW MANY POUNDS DO YOU WANT TO LOSE? NO PROBLEM.

LET ME TELL YOU ABOUT OUR COMPANY. WE'RE A HEALTH AND NUTRITION COMPANY THAT SPECIALIZES IN HERBAL WEIGHT CONTROL. OUR PROGRAM IS COMPLETELY NATURAL AND IS VERY HEALTHY FOR YOU. IT CONTAINS ALL OF THE AMINO ACIDS AND VITAMINS AND MINERALS THAT YOUR BODY NEEDS ON A DAILY BASIS. IT ALSO CONTAINS A SPECIAL BLEND OF OILS TO HELP TIGHTEN THE SKIN AS YOU LOSE WEIGHT. AND SOMETHING ELSE THAT IS EXCITING ABOUT THIS EFFECTIVE PROGRAM IS THAT IT CONTAINS 14 HERBS THAT VERY NATURALLY SUPPRESS THE APPETITE AND CLEANSES YOUR SYSTEM. THE PRODUCT COSTS ABOUT $1.10 PER MEAL WHICH YOU WOULD SUPPLEMENT TWO MEALS A DAY, SO THAT YOU SAVE ON YOUR FOOD BILL AT THE SAME TIME. WE PERSONALIZE THE PROGRAM TO FIT YOUR NEEDS AND LIFESTYLE.

THE AVERAGE WEIGHT LOSS IS 10-30 POUNDS A MONTH. WHEN WOULD BE A GOOD TIME FOR A CONSULTANT TO STOP BY AND SHOW YOU THE PRODUCT... DAYTIME OR EVENING?

WEAR YOUR BUTTON AT ALL TIMES !

RESPONSE WHEN SOMEONE ASKS YOU: "HOW DO YOU LOSE WEIGHT?"

ASK THEM THE FOLLOWING QUESTIONS:

1. ARE YOU REALLY INTERESTED IN LOSING WEIGHT? (IF ANSWER IS NO, THEN STOP ANY FURTHER CONVERSATION BECAUSE YOU ARE WASTING YOUR TIME.)
2. HOW MANY POUNDS DO YOU WANT TO LOSE?
3. HAVE YOU EVER TRIED TO DIET BEFORE?
4. WHY DID IT FAIL? (USUAL RESPONSES ARE: I PUT THE WEIGHT BACK ON, I GOT HUNGRY, I GOT TIRED OF THE TASTE, ETC.)

IF I COULD SHOW YOU A PROGRAM THAT SUPPLIED ALL OF THE DAILY NUTRITIONAL NEEDS, AND YOU COULD LOSE 10-29 POUNDS PER MONTH, IS 100% MONEY BACK GUARANTEED, AND (COUNTER THEIR REASON FOR FAILURE) WOULD YOU BE INTERESTED IN HEARING ABOUT IT?

WHICH IS BETTER FOR YOU ... TOMORROW MORNING AT 9:30 OR THURSDAY EVENING AT 7:00 ?. (ALWAYS GIVE TWO CHOICES FOR THE APPOINTMENT.)

SALES AD RESPONSE

GOOD MORNING, MAY I HELP YOU?
("YES, I'M CALLING ABOUT THE AD.")
OKAY, WHAT IS YOUR NAME PLEASE? AND WHAT IS YOUR PHONE NUMBER WHERE YOU CAN BE REACHED? FINE. JUST A COUPLE OF QUESTIONS, (THEIR NAME) .

DO YOU HAVE ANY TYPE OF SALES EXPERIENCE OR MANAGEMENT BACKGROUND?
(OH, THAT'S GREAT, IN WHAT FIELD?)
IS THAT THE TYPE OF WORK YOU ARE DOING NOW?

OKAY. LET ME TELL YOU ABOUT OUR COMPANY AND EXACTLY WHAT WE'RE LOOKING FOR. THE NAME OF OUR COMPANY IS , AND IT IS A VERY EXCITING COMPANY FOR A LOT OF REASONS; ONE IS THAT OUR COMPANY IS GROWING VERY FAST SO THERE ARE A NUMBER OF TOP POSITIONS AVAILABLE RIGHT NOW. AND THE MAIN THING WE DO IS MARKET HEALTH AND NUTRITIONAL PRODUCTS WHICH ARE IN BIG DEMAND.

THE MAIN THING WE ARE LOOKING FOR RIGHT NOW, (THEIR NAME) , ARE SOME KEY PEOPLE WHO CAN HELP US DEVELOP, TRAIN AND SUPERVISE GROUPS OF PEOPLE TO GO OUT AND PRESENT OUR PRODUCTS. SOME OF THE PEOPLE WE HAVE WORKING WITH US NOW MAKE 3 TO 5 THOUSAND DOLLARS A MONTH. DOES THIS SOUND LIKE SOMETHING THAT COULD POSSIBLY HOLD SOME INTEREST FOR YOU?

(BE QUIET AND WAIT FOR RESPONSE.)

ALL OF THE INTERVIEWING WILL BE GOING ON THIS EVENING, SO LET ME GIVE YOU THE ADDRESS AND DIRECTIONS (THEIR NAME) . DO YOU HAVE A PEN?

OKAY, IT'S ____________________.

ARE YOU FAMILIAR WITH THE AREA? FROM WHAT AREA OR FREEWAY ARE YOU COMING AND I WILL GIVE YOU EXACT DIRECTIONS.

AND YOU WILL NEED TO BE THERE AT ____________ SHARP. WHEN YOU COME IN THERE WILL BE A RECEPTIONIST THERE AND JUST ASK FOR ME, (YOUR NAME) .

IF YOU CAN COME IN A LITTLE EARLY IT WILL GIVE ME A CHANCE TO GREET YOU.

OKAY, (THEIR NAME) , I'M LOOKING FORWARD TO MEETING YOU (DAY)
AT ____________ P.M.

WHAT SYMPTOMS TO EXPECT WHEN YOU IMPROVE YOUR DIET

by

Dr. Stanley S. Bass, N.D., D.C., Ph.C.

If I were asked which is the area of greatest misunderstanding and confusion in the field of nutrition, I would immediately be forced to reply, it is the failure to properly understand interpret the symptoms and changes which follow the beginning of a better nutritional program.

What is meant by a better nutritional program? It is the introduction of foods of higher quality in place of lower quality ones. For example, if a person replaces a protein rich food such as pork with beef, the beef may be considered the superior of the two due to its easier digestibility, lower and less saturated fat content, etc.; chicken is superior to beef and fish is superior to chicken because of its more rapid digestibility and lower saturated fat content. Lima beans, lentils or chick peas, which are eaten at the same meal with vegetables, are superior in all the nutrients needed to rebuild health. As we go higher in the scale of quality, we begin to include protein rich food which may be eaten in the unfired state, such as cheese which is made from raw milk and unsalted. Then we ascend to the nuts and seeds which are eaten in the natural state (raw and unsalted). To summarize: the closer the food comes to the natural state in which it occurs, or the closer we come to its raw, unfired form, the higher its quality. In this condition, all the enzymes are found intact. The amino acids are in their finest form. The minerals, vitamins, trace elements, carbohydrates and "life force" are present. The life force, in turn, is capable of reproducing healthy tissue.

This same classification of quality which we analyzed in relation to protein rich foods applies to the carbohydrates (the starches and sugar-rich foods), the fats and the mineral-rich foods.

The quality [illegible] a nutritional program is also improved by OMITTING toxic substances such as coffee, tea, chocolate, tobacco, salt, pepper, etc.

What is the relation of quality of foods to recovery from illness? It is this in a nutshell: the HIGHER the quality of food is that we eat, the QUICKER we recover from disease provided we are able to properly digest and assimilate properly. To this must be added the knowledge of (a) proper food combining, (b) proper order of eating the different kinds of food at a meal; e.g., the most easily digested food should be eaten first, the more complex one second, and the most concentrated item last, (c) the correct quantity of food to be consumed (of each type) in the meal, and (d) the correct time for eating (when hungry, and not by the clock).

Now, what happens when a person follows these rules and makes a decided improvement in the quality of the food consumed? Remarkable things begin to happen to the body as well as the mind. The amazing intelligence present in every cell of the body and the wisdom of the body in its operation immediately becomes manifest. The rules may be stated thusly: when the quality of the food coming into the body is of higher quality than the tissues which the body is made of, the body begins to discard the lower grade materials and tissues to make room for the superior materials which it uses to make new and healthier tissue. This is the plan of NATURE. The body is very selective and ALWAYS aims for improvement for better health. The body ALWAYS tries to produce health and ALWAYS will, unless our interference is too great. Only then do we fail to recover and degenerate further into disease. The self-curing nature of many conditions such as colds, fevers, cuts, swellings, injuries, etc., furnishes endless examples of how the body tends towards health--ALWAYS--unless we do something to stop the process.

What are the symptoms or signs which become evident when we first begin to omit the lower grade foods and instead introduce superior foods---those which are more alive, more natural than we are accustomed to? When the use of a toxic stimulant such as coffee, tea, chocolate or cocoa is suddenly stopped, headaches are common and a letdown occurs. This is due to the discard by the body of the toxins called caffeine and theobromine which are removed from the tissues and transported through the blood stream during its many bodily rounds. Before the noxious agents reach their final destination for elimination, these irritants register in our consciousness as pain--in other words, headache. The letdown is due to the slower action of the heart--the resting phase which follows the stimulation of more rapid heart action forced upon the body by certain poisons called stimulants. The more rapid heart beat (or pulse) produces a feeling or exhilaration, and the slower action produces a depressed state of mind. Usually, within three days, the symptoms vanish and we feel stronger due to the recuperation which follows.

To a lesser extent, the same process occurs when we abandon lower quality foods and replace them with better foods. Lower quality foods have undergone more preparation. Spices, salt and other ingredients have been added, as they ten to be more stimulating than less prepared and more natural foods. Animal foods such as meat, fowl, fish, etc. are more stimulating than cheese, nuts and vegetable proteins. Consequently, the withdrawal of stimulation which follows the abandonment of animal food produces a slower heart action---a resting phase---which registers in the mind as relaxation or a decrease in energy. This inital letdown lasts about ten days or slightly longer and is followed by an increase of strength, a feeling of diminishing stress and greater well-being.

Now, let us return to the symptoms which occur in the process of regeneration.

The person who starts a better diet, stays on it for three days to a week and then quits will say, "Oh! I felt better on the old diet--the new one made me feel weak." He failed because he didn't give his body a chance to adjust and complete its first phase of action--recuperation. If he had waited a while longer, he would have begun to feel better than before he started.

During this initial phase (lasting about ten days on the average to several weeks in others), the vital energies which are usually in the periphery or external part of the body such as the muscles and skin, begin to move to the vital internal organs and start reconstruction. This shunting of much of the power to the internal region produces a feeling to less energy in the muscles, which the mind interprets as some weakness. Actually, the power is increased, but most of it is being used for rebuilding the more important organs and less of it is available for muscular work. Any weakness which is felt here is not true weakness, but merely a redeploying of forces to the more important internal parts. Here it is important for the person to stop wasting energy, and to rest and sleep more. THIS IS A CRUCIAL PHASE, and if the person resorts to stimulants of any kind, he will abort and defeat the regenerative intent of the body. It is important that he have patience and faith and just wait it out, and after awhile he will get increasing strength which will exceed by far what he felt before he began the new program. Success in recovery or improvement of health hinges upon the correct understanding of this point--REALIZING that the body is using its main energies in more important internal work and NOT wasting it in external work involving muscle movements. Be wise--take it easy here and relax. Just coast in your work and social obligations until you are out of the woods.

As one continues on the improved diet and gradually raises the food quality, interesting symptoms begin to appear. The body begins a process called "retracing". The cellular intelligence reasons something like this: "Oh! Look at all those fine materials coming in. How wonderful--now we have a chance to get rid of this old garbage and build a beautiful new house. Let's get started immediately. Let's get this excess bile out of the liver and gallbladder and send it to the intestines for elimination. Let's get this sludge moving out of the arteries, veins and capillaries. These smelly, gassy, brain-stupefying masses have been here too long--out with them! These arthritic deposits in the joints need cleaning up. Let's get these irritating food preservatives, aspirins, sleeping pills and drugs out of the way along with these other masses of fat which have made life so burdensome for us for so long. Let's get going and keep going till the job is done--till we have a beautiful house--and from then on we'll keep it beautiful.

During the first phase (called catabolism), the accent is on elimination, or breaking down of tissue. The body begins to clean house--in short, to remove the garbage deposited in all the tissues--everywhere. During this period, the body "removes the ashes from the furnace preparatory to getting a better fire." Here the accentuation is on removal of the gross and immediate body obstructions. Wastes are discarded more rapidly than new tissue is made from the new food. This becomes evident as weight loss. This persists for a while and is then followed by the second phase--stabilization.

Here, the weight remains more or less stable. During this phase, the amount of waste material being discarded daily is equal to the amount of tissue which is being formed and replaced by the newer, more vital food. This occurs after the excess of obstructing material in the tissues has been removed. This stage persists for awhile and is then followed by a third phase--a build-up period (called anabolism), wherein weight starts to go up, even though the diet is lower in calories than it was before. At this point, much or more of the interfering wastes have already been discarded--the tissues which have been formed since the diet was raised in quality are more durable and do not break down easily. Also, new tissues are now being formed faster. This is due to the improved assimilation made possible by the ceasing of wrong food-combining. The body's need for the usual amounts of food decreases, and we are able to maintain our weight and increased energies with less food. Many are able to function very efficiently on two meals a day and eventually even on one meal a day. As the body progressively increases in efficiency and decreases in tissue breakdown under exercise, so do we gradually need less and less food to maintain life. The higher the percentage of raw food one lives on, the slower the rate of tissue deterioration which one evolves into. A sick body requires a gradual, carefully worked-out entry into this stage, where one is able to live on a 100% unfired (raw) diet.

Returning to the symptoms which occur on a superior nutritional program--people who have had tendencies in the past to recurring skin rashes or eruptions will frequently tend to eliminate poisons and harmful drugs through the skin with new rashes or eruptions. If they go to a doctor now who is not familiar with this aspect of nutrition, he will diagnose it as an allergy. They ask, "How come: I'm eating better now than I ever did before, and instead I'm getting worse?" They don't understand that the body is "retracing." The skin is getting more alive and active. It's throwing out more poisons more rapidly now that the body is building more power which is saved from those hard-to-digest meals which have been discontinued. These toxins being discarded are saving you from more serious disease which will result if you keep them in your body too much longer--possibly hepatitis, kidney disorders, bllod disease, heart disease, arthritis, nerve degenerations or even cancer--depending upon your hereditary or structural weaknesses. Be happy you are paying your bills now in an easy-payment plan.

With some, colds which haven't appeared for a long time may occur, or even fevers. THIS IS NATURE'S WAY OF HOUSECLEANING. Understand that these actions are constructive, even though unpleasant at the moment. DON'T--but DON'T try to stop these symptoms by the use of certain drugs, or even massive doses of vitamins which will act as drugs in huge concentrations. These symptoms are part of a curing process, and don't try to cure a cure. These are NOT deficiency conditions or allergic manifestations--NOT if you are eating properly in quality, quantity, combination and sequence. Here is where experienced advice is a great value. Unfortunately, there are few books present today which give full guidance to the average reader. Try to find guidance through a doctor or teacher who has the requisite experience in this most confusing of all subjects--nutrition in relation to health and disease.

You may be eating perfectly in regard to quantity, quality, and observing all the correct rules, and still symptoms will occur. Those who have lived better lives in the past--who have eaten better foods and who have abused their bodies less with over-eating will have reactions ranging from almost none at all or very mild to symptoms which may be uncomfortable or acute. Those who have lived worse lives and poisoned themselves more will experience more severe symptoms if their liver, kidneys, or other important eliminating organs have been damaged. When they have been renovated to the point of fair working order, they will no longer produce symptoms.

Headaches may occur at the beginning; fever and/or colds also may appear; the skin may break out; there may be a short interval of bowel sluggishness, occasional diarrhea, feelings of tiredness and weakness, disinclination to exercise, nervousness, irritability, negativity or mental depression, frequent urinations, etc.,etc. However, the great majority of people find their reactions tolerable and are encouraged to bear with them because of the many improvements which have already occurred and are becoming more evident with each day. This acts as an inspirational force to them.

The symptoms will vary according to the materials being discarded, the condition of the organs involved in the elimination, and the amount of energy you have available. The more you rest and sleep when symptoms are present, the milder they are and the more quickly they are terminated. Be happy you are having symptoms. REALIZE DEEPLY that your body is becoming younger and healthier every day because you are throwing off more and more waste which would eventually have brought pain, disease and much suffering. Those who have the worst symptom-reactions and follow through to their successful termination are thus avoiding some of the worst diseases which would eventually have developed had they continued their careless eating habits.

Don't expect to go on an ascending scale of quality--that improving your diet will make you feel better and better each day until you reach perfection. The body is cyclical in nature, and health returns in a series of gradually-diminishing cycles. For example --you start a better diet and for awhile you feel much better. After some time, a symptom occurs--you may feel nauseous for a day and have diarrhea with a foul-smelling stool. After a day, you feel even better than before and all goes fine for awhile. Then you suddenly develop a cold, feel chills and lose your appetite. After about two months, when you suddenly develop an itch or rash. You still don't take anything special for it. This rash flares up, gets worse and continues for ten days, and suddenly subsides. Immediately after this your energy has increased more than ever before. The rash became an outlet for the poisons in the liver. This is how recovery occurs--like the cycles in the Dow-Jones Average at the beginning of a bull market recovery. You feel better, a reaction occurs and you don't feel as well for a short while. You recover and go higher for awhile. Then another reaction occurs--milder than the last. You recover and go even higher. And so it goes--each reaction milder than the last as the body become purer, each becoming shorter in duration and being followed by a longer and longer period of feeling better than ever before, until you reach a level plateau of vibrant health. Here you become relatively disease-free and are filled with ever-increasing joy, life and the happiness which comes from sheer well-being. The first laws we must learn to obey are the laws of Nature. We must learn to eat simple, pure and natural foods, properly prepared and combined, and our bodies in return will cast off all the evil we have taken in during our lives. All repentance must begin here in the body--trhough pure diet and natural foods. Then, just have faith, sit back and watch what happens. Before your own eyes, you will daily see signs that will cause you to wonder at this vast intelligence in operation that staggers the comprehension. Let us give ourselves a chance to experience what it means to be really healthy and fully alive--to feel the joy of living by aligning ourselves to God's (Nature's) laws as intended for man--through the eating of natural (normal) foods. This indeed is the prime prerequisite in man's physical, mental and spiritual unfoldment.

CARBOHYDRATES: YOUR BODY'S PRIMARY FUEL.

Carbohydrates are the primary energy source for all body functions and muscular exertion, and are necessary to assist in the digestion and assimilation of other goods. They provide the body with immediately available calories for energy by producing heat in the body when carbon in the system combines with oxygen in the bloodstream. Carbohydrates also assist in the regulation of protein and fat metabolism: fats require carbohydrates for their breakdown in the liver.

Starches, sugars and cellulose are the principal carbohydrates. From the starches or polysaccharides; which are chains of simple sugars, come the body's most efficient fuel. Starches such as grains, legumes and vegetables, for instance, are easily digested and converted to glucose, which is then carried by the blood to all cells of the body. Whole grains and legumes also offer the advantage of supplying the B vitamins your body needs in order to burn glucose as fuel.

FATS: YOUR CONCENTRATED ENERGY SOURCE.

Fats make up another class of compounds that serve mainly as an energy source. Fats must be "emulsified" before they can be absorbed by the body because in contrast to the digestive system, which is primarily water based, fats are not water soluble. Emulsification is essentially a process by which fatty materials are made water dispersible by combining with the bile acids which act as emulsifying agents. In addition of being a concentrated source of energy, fats serve certain structural functions, such as being a part of all cell membranes and providing insulation and protection for all internal organs.

Basically, food supplies two types of fat, both of which are important to good health; saturated and unsaturated. These are classified according to the hydrogen atom content of their fatty acid chains. Saturated fatty acids are those that are usually solid at room temperature and which,except for coconut oils, are derived primarily from animal sources: meat, butter, milk products and egg yolk. Unsaturated fatty acids, which include polyunsaturates, are generally cholesterol free and are usually liquid at room temerature. They come from a variety of sources: vegetable, vegetable oils, margarines and nuts.

There are three fatty acids which are commonly designated as "essential": linoleic, arachidonic and linolenic. These unsaturated fatty acids are important for the health of the blood, arteries and nerves, and are also necessary for normal growth. Pure, natural vegetable oils---safflower, sunflower, soybean, wheat germ and cottonseed---are the best sources.

Cholesterol is a fatlike substance which is found in every body cell. Part of the cholesterol in our body comes from food, but even more of it is manufactured by the body. Since cholesterol is found only in animal fats and not in vegetable fats, food choices can affect the cholesterol level in your body.

PROTEINS: THE BODY BUILDERS

Proteins are one of the most important elements for the maintenance of good health and the growth and rebuilding of all body tissues. They are also the major source of building material for muscles, blood, skin, hair and internal organs, including the heart and brain. Proteins are actually complex molecules made up of smaller structures called amino acids. The body requires approximately twenty two amino acids. Fourteen of these can be produced in the adult body: the eight that cannot be produced are called "essential" amino acids because they must be supplied in the diet.

When a food contains all the essential amino acids, it is a "complete protein": foods that are low in some of the essetial amino acids (or lack them totally) are called "incomplete proteins". Most meat and dairy products are complete protein foods, while the majority of fruits and vegetables are incomplete protein foods. However, some vegetable proteins are good sources of essential amino acids and are high quality proteins. Examples are yeast, soybean protein and peanut protein (such as that obtained from peanut butter.

Although a single food may be a "low quality" protein source, when combined with another "low quality" protein, the result can be of very good value, since one complements the amino acid content of the other. An example is cereal combined with milk because it provides maximum effective use of the amino acids present in both. Other examples include macaroni and cheese, casserole dishes combined legumes with small amounts of meat, and sandwiches that combine cereal grains, vegetables and cheese.

VITAMINS: CATALYSTS TO GOOD HEALTH

Vitamins are a group of organic compounds that are necessary for the normal metabolism of other nutrients. They perform an important role as co-enzymes and they act as catalysts to facilitate the reactions that cause nutrients to be used for energy, building cells or maintaining cells and tissue.

Vitamins are either water-soluble or fat-soluble, characterized by the manner in which they are absorbed by the body. Most vitamins are water-soluble, which means they can be transported by the blood and absorbed by the cells where they are needed. The water-soluble vitamins such as Vitamin C and the B-Complex, cannot be stored by the body and any excess is eliminated in the urine. Therefore, the body's supply must be replenished on a regular daily basis.

In contrast to water-soluble vitamins, fat-soluble vitamins (like Vitamins A,D, and E) can be stored in your body. If your dietary intake of these nutrients is inadequate, then the need for these reserves becomes critical. One of the best known and most publicized fat-soluble vitamins is Vitamin E. However, there has been some confusion as to which forms are natural and which are synthetic. As a basic guideline, the natural form of Vitamin E is usually designated by the prefix "d-alpha."

In contrast to fats, carbohydrates and protein, a vitamin has no inherent energy or caloric value. Also, with a few exceptions, these vital organic compounds cannot be manufactured by the body; they must be supplied in the diet or through supplementation. Vitamins work as a team in your body, interacting with each other. To be effective they usually require the presence of another vitamin or nutrient. For example, Vitamin E and zinc protect Vitamin A for absorption and utilization in the body.

MINERALS: SIMPLE BUT VITAL NUTRIENTS

Minerals are inorganic and simple compounds that make up 4-5% of your total body weight. Minerals play a more important role in the body than their quanities might indicate. In combination with organic compounds, they are constituents of vitamins, hormones, and enzymes as well as cells and especially the hard tissues like bones and teeth.

The body requires approximately 17 essential minerals to contribute to vital bodily functions. Without minerals, vitamins cannot function in the body. Minerals are divided into two main groups; based on their quantity in the body. Macrominerals is the name for minerals that are required and present in the body in large amounts. Calcium is a good example since it is present in the body in greater amounts than any other single mineral element, and is vitally important to the health of teeth and bones.

Trace minerals (microminerals) such as zinc and iron, are also needed in the body, but in lesser amounts. Iron, the most abundant trace mineral is found in every tissue cell and is extremely valuable to the quality of the blood. Zinc is the second largest quantity trace mineral and is related to the normal absorption and action of vitamins especially the B-complex.

BLUE SUPPLEMENTAL TRAINING BOOKLET

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EXHIBIT NO. 15

Cambridge plan

ROBERT O. NESHEIM, Ph.D.
VICE PRESIDENT
SCIENCE & TECHNOLOGY
RESEARCH & QUALITY ASSURANCE

160 CENTRAL AVENUE, PACIFIC GROVE, CA 93950 TELEPHONE (408) 373-2300

June 21, 1985

PERM. SUBCOMMITTEE
RECEIVED
JUN 24 1985
ON INVESTIGATIONS

Daniel F. Rinzel
Chief Counsel and Staff Director
Permanent Subcommittee On Investigations
United States Senate
Washington, D.C. 20510

Dear Dan:

We wish to add this letter to the record of the May 15, 1985, hearing on the Investigation of Weight-Control Products before the Permanent Subcommittee on Investigations.

During the hearing, Mr. Vaughn Feather agreed to supply to the Subcommittee written materials instructing distributors of the Cambridge Diet to make consumers aware of the medical notice on the container of the Diet and to direct consumers to see their physician before dieting. Accordingly, we enclose:

1. Those pages from our Area Distributor Manual (Revision dated May 1984) in which instructions or reference to physician consultation is made as a part of the training of Area Distributors.

2. Those pages from the Counselor Training Manual which instruct them in the role of the physician in our weight-management program.

3. The copies of Nutrition and Medical Bulletins illustrating the type of communication that is sent periodically to Area Distributors from that department, with emphasis on working with physicians in our weight-management program.

At the hearing, there was also a discussion concerning the medical supervision of dieters using the Cambridge Food For Life Program. We recommend unequivocally that persons starting on our weight-loss program should consult with their physician. This is repeated throughout the Program Book which was submitted at the hearing, and it is also stated in the inserts which are contained in each can of our products. (Since we did not include these in our previous submissions, a copy of the can inserts for each of three principal products is enclosed.) As stated above, our Area Distributors are instructed to advise customers to consult their physician before dieting.

In addition to the recommendation to consult with a physician before starting on the Cambridge Diet program, a medical notice is placed on the label of each container of Cambridge Diet products providing less than 800 calories per day, and is printed on the can insert contained in each can of all products. The promotional literature for the Cambridge Food For Life Program also carries the medical notice.

Cambridge Plan International (CPI) believes that as a matter of policy, such a notice should be provided on all weight-loss diet formula products providing less than 800 calories per day. This serves to alert consumers about potential risk of dieting when they have a pre-existing medical condition, and will encourage dieters to consult with their physician before starting a significant weight-loss program.

Following the testimony of Vaughn Feather and Robert O. Nesheim, it was asked why CPI was continuing to sell the original 330-per-day Cambridge Diet since we now recommend an 800-calorie diet program. A full answer follows.

The original Cambridge Diet provided 330 calories per day with 75 percent of the U.S. RDA for protein, and 100 percent of the U.S. RDA for all other nutrients. In 1983 we learned from a survey that over 80 percent of persons using this product on a weight-loss program were consuming at least one meal per day in addition to the Cambridge Diet, and that this produced a satisfactory weight loss. Following weight loss, a large number of Cambridge users were taking the original Cambridge Diet as a nutritional supplement along with other food in a weight-maintenance program. These users were pleased with the original Cambridge Diet as a nutritional supplement or an occasional meal replacement in their weight-maintenance programs.

Our current directions for use accordingly recommend that the Cambridge 330 product be used with a small meal which essentially assures consuming the full U.S. RDA for protein and raises the total caloric intake to 800 calories or more. This program, including use of the Cambridge 330 Diet, is the most economical of our weight-loss programs. Based on the long history of safe and effective use, combined with the pattern of use, cost-effectiveness, and many satisfied users, we concluded the original Cambridge Diet should be preserved as a part of a revised 800-calorie-per-day program.

A number of witnesses at the hearing were asked whether further statutory authority or FDA regulations were required to protect the public from unsafe or fraudulent diet products. Senator Roth characterized this as "the sixty-four dollar question" before the Subcommittee. Because CPI's witnesses did not have a chance to answer this question, and because our views may differ from those of the other witnesses, we would like to state them.

Much of the current concern about the safety of very-low-calorie diets (VLCD) for weight loss comes from the serious problems including many deaths that were attributed to "Liquid Protein" diets sold in the mid to late 1970s. Although the two differ in material respects, much of the harsh criticism and consequent alarm of the Cambridge Diet stems from the liquid protein experience. In our view, the liquid protein diets were brought to the market with wholly inadequate research and clinical evaluation. That a dangerous diet product of this kind could be freely distributed in this country without prior clinical evaluation certainly suggests a gap in the then existing regulatory scheme.

It is true that current FDA labeling regulations require warnings on diet products of less than 400 calories which derive over 50 percent of their calories from protein, and that those regulations were not in effect at the time of the liquid protein problem. However, those labeling regulations address only part of the diet formula products. Given the public's demonstrated appetite for diet products which are new and different, it seems reasonable to expect that the next dangerous diet will be one which is a departure from past products, and it may well fall outside current regulations.

The original Cambridge Diet does not fall under the current labeling regulations because it derives more than half of its calories from carbohydrate, not protein, and in our Cambridge 420 and 800 products, provides over 400 calories per day. Under a different and tighter regulatory scheme, the original Cambridge Diet might have been required to meet reasonable standards of prior research and clinical testing, and we would have had no objection to that. Indeed, for commercial reasons, we would have welcomed the chance to demonstrate the safety of the Cambridge Diet because then it might not have been equated loosely with the poor quality liquid protein diets marketed in the 1970s. In a sense, the absence of tighter diet formula product regulations has harmed our product in the market.

It seems appropriate, therefore, to consider regulations on formula diet products that at least assure adequate levels of required nutrients as established by the National Academy of Sciences, coupled with a medical notice in the product label. We believe this would provide additional protection for the consumer and would also distinguish appropriately formulated and well-tested products from those which are potentially dangerous.

We would, of course, be willing to work with the responsible government agencies on this matter in any appropriate way.

Sincerely,

Robert O. Nesheim, Ph.D.

RON:psp

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DANIEL F. RINZEL, CHIEF COUNSEL
ELEANORE J. HILL, CHIEF COUNSEL TO THE MINORITY

June 19, 1985

Dr. Frank Young
Commissioner, Food and Drug
Administration
5600 Fishers Lane
Room 14700
Rockville, MD 20857

Dear Dr. Young:

On behalf of the Permanent Subcommittee on Investigations, I would like to extend my appreciation for your appearance before the Subcommittee on May 15. The Subcommittee remains interested in the course of the FDA's review of various weight reduction products, and I would ask that the staff of the Subcommittee be kept apprised of the FDA's investigation of these products.

There are also several specific statements which were made during the hearing which generate concern. For instance, Mr. Taylor stated that kava kava is illegal to sell in the United States and the FDA has not done anything to prevent its sale in one of the Herbalife products. Could you provide the Subcommittee with a reason for this inaction? Mr. Taylor also stated that comfrey is listed as having "undefined safety." Could you explain what this phrase signifies? Additionally, Mr. Taylor said that the agency would have to check on the safety on NDRG, which is found in chaparral. Has this check been done, and what is the result? I would also point out that during his testimony, Mark Hughes (Herbalife President) stated that the FDA had found comfrey and chapparral to be "perfectly safe" and that the FDA is clearly not concerned with the potential dangers of selenium found in Herbalife products. Are these statements accurate?

We would also like to have an update on the current number of complaints which FDA has received concerning Herbalife products.

Senator Gore has asked that the following follow-up questions be responded to in writing:

1. Does the FDA have any precise target date at which time a decision will be made with respect to Herbalife?

2. At the Subcommittee's hearings, the FDA stated that there were additives that were present in Herbalife's products that were not GRAS, yet the FDA had taken no action with respect to those additives. Is any action intended?

3. What is the current status of the seizure action which was recommended in September, 1983, and placed in temporary abeyance in November, 1983? Has that recommended action been rejected? Is it still in temporary abeyance?

4. During Mr. Hughes' testimony before the Subcommittee, he stated on a number of occasions that the FDA's preceding testimony had given his products a clean bill of health, and that the FDA had approved of his products. Would you agree with that assessment? Does the FDA take exception to such statements?

Please direct your responses to this letter and any other questions to Daniel F. Rinzel, Chief Counsel for the Subcommittee.

Sincerely,

Bill Roth

William V. Rotn, Jr.
Chairman

WVR,JR:hsw

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 31, 1985

The Honorable William Roth
Chairman, Permanent Subcommittee
  on Investigations
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Senator Roth:

I write to respond to your letters of June 19 and October 8 concerning Herbalife weight reduction products. Please accept my apology for the delay in responding to your earlier letter.

Enclosed is a report that responds to each of your, and Senator Gore's, questions about the Food and Drug Administration's regulation of Herbalife products. Also, we are examining Ms. Huston's complaint and will prepare a detailed reply to her. We will send you a copy of that response.

I would like to update you as well on recent efforts to resolve our concerns with Herbalife. At the firm's request, my staff and I met with its President, Mark Hughes, his general counsel and other members of his staff both on October 9 and again on October 22 to discuss Herbalife's labeling practices, literature produced by Herbalife distributors, and progress of the firm's voluntary recall of certain promotional literature.

At those meetings, we learned of Herbalife's success in working to effect that recall of literature as well as future commitments, its description of procedures for terminating its relationship with dealers who violate company standards of conduct, its promise to further notify dealers of potential advertising problems and its commitments to work with FDA on labeling changes. Other meetings with representatives of the firm and senior program staff of this Agency are being scheduled to discuss and resolve remaining issues.

We am encouraged by Herbalife's willingness to respond positively to the questions raised by the FDA. With their successful resolution, the public health concerns the Agency had regarding the firm's products should be answered.

Please let me know if you need further information.

Sincerely yours,

Frank E. Young

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure
Report

RESPONSES TO QUESTIONS CONCERNING HERBALIFE

Senator Roth's Questions

1. Could the FDA provide the Subcommittee with a reason for this inaction (to prevent the sale of Kava Kava in the United States)?

The FDA has historically regulated the importation of the herb Kava Kava--because it is not an approved food additive nor the subject of a regulation exempting it from being approved as a food additive. Although the Agency has attempted to detain all lots offered for entry, shipments will occasionally pass through our surveillance and be found as a constituent in herbal preparations. We are now considering what additional steps to take relative to Kava Kava. A complete review of the scientific literature concerning that substance is being conducted, and the Agency's decisions on possible regulation will be formally announced in the Federal Register. We will keep you apprised of our actions.

2. Mr. [John] Taylor also stated that comfrey is listed as having "undefined safety." Could you explain what this phrase signifies?

FDA's toxicologists know that comfrey naturally contains pyrrolizidine alkaloids, which are carcinogens, and it is known that consumers should not ingest large amounts of comfrey over long periods of time. But we cannot conclude that the amount of comfrey in "Herbal Aloe," an Herbalife product, or other similar products on the market today, is sufficient to present a hazard to human health from cancer. Notwithstanding any statements you have received to the contrary, FDA has not "found" comfrey to be "perfectly safe."

3. Mr. Taylor said that the Agency would have to check on the safety of NDRG, which is found in chapparral. Has this check been done, and what is the result?

"Chaparral" is not a specific plant, but rather a general name given to a variety of woody, husky plants. Because FDA has no information on the exact identity or quantity of the ingredient "chaparral" in Herbalife products, action could not be taken against a product containing that ingredient until we could demonstrate that it contains a prohibited substance. We are now in the process of obtaining a reference standard and sufficient sample to do an analysis of Herbalife's "chaparral" ingredient. Attached (Tab A) for your information is a copy of the Canadian study of Nordihyroguaiaretic Acid (NDGA) that was the basis for removing that substance from the Generally Recognized As Safe (GRAS) list. FDA has not found "chaparral" to be safe, notwithstanding any statements you have received to the contrary.

4. I would also point out that during his testimony, Mark Hughes stated that the FDA . . . is clearly not concerned with the potential dangers of selenium found in Herbalife products. (Is that) statement correct?

The selenium content of Herbalife products do not appear to exceed the recommended total daily intake. Since the safe and suitable range of selenium intake was established by the National Academy of Sciences at 50-200 micrograms (mcg), we are not pursuing regulatory action against products that do not exceed 200 mcg as the suggested daily intake, and which contain safe and suitable forms of the mineral. However, we continue to monitor the use of this substance for any evidence that might lead us to adopt a different regulatory position.

5. We would also like to have an update on the current number of complaints which FDA has received concerning Herbalife products.

By mid-September, the Agency had received and reviewed approximately 150 complaints of which 83 could be substantiated. While the reported symptoms could theoretically be associated with a number of factors, including diet change or perhaps the pharmacological action of the herbs in the Herbalife products, the concentrations of those herbs at recommended dosage levels would not be anticipated to produce an adverse reaction. Thus, to the best of our knowledge, current Herbalife products do not contain concentrations of herbs that pose a risk of health hazard to consumers. To date we have also investigated ten additional complaints alleging that Herbalife products were involved in fatalities. These have been extensively reviewed in terms of the epidemiological evidence and associated pathology. After an indepth analysis that compared the use of Herbalife products with the onset of symptoms and with the victim's medical records, none of the available evidence permits the conclusion that a link exists between the consumption of Herbalife products and those fatalities.

Senator Gore's Questions

1. Does the FDA have any precise target date at which time a decision will be made with respect to Herbalife?

As stated in the body of the letter transmitting this report, FDA officials met with Herbalife representatives on October 9 to discuss Herbalife's promotional and labeling practices. A number of issues were resolved, and a second meeting was held on October 22 to discuss labeling changes for Herbalife products. Real progress was made at this second meeting as well, and as is consistent with our policies in all such situations, we will continue to monitor progress periodically. We will inform you if there is any significant reduction in Herbalife's level of cooperation in this effort.

2. At the Subcommittee's hearing, the FDA stated that there were additives that were present in Herbalife's products that were not GRAS, yet the FDA had taken no action with respect to those additives. Is any action intended?

As part of the examination of several firms' herbal products, we are reviewing the status of the substances in those products that are not GRAS. We will, of course, take appropriate action against any found to be harmful.

Our current list of herbs that we consider unsafe includes 27 herbs. Since that list was developed several years ago, a number of scientific studies have been completed that could affect their regulatory status. Therefore, we are re-evaluating our compliance policy dealing with the status of those and other herbs for food uses. It is important to note that a major consideration in evaluating the safety of any herb in a given product is the amount of the herb in that product.

3. What is the current status of the seizure action that was recommended in September 1983, and placed in abeyance in November 1983? Has that recommended action been rejected? Is it still in temporary abeyance?

The September 30, 1983 seizure recommendation was placed in temporary abeyance on November 28, 1983, pending clarification of the Agency's policy toward food/drug products that contain vitamins, minerals or herbs, and are promoted with therapeutic claims. As we testified in May, the policy was clarified in June 1984 (Tab B). Since the lot of products that was the subject of the seizure recommendation was distributed many months prior to that time, we consider that recommendation moot, and have closed the file on that particular action.

4. During Mr. Hughes' testimony before the Subcommittee, he stated on a number of occasions that the FDA's preceding testimony had given his products a clean bill of health, and the FDA had approved of his products. Would you agree with that assessment? Does the FDA take exception to such statements?

FDA takes exception to the statement. The Agency has no authority to approve any food products except for food and color additives as ingredients of foods. The Agency has no program of product endorsement.

2 Attachments

Fd Cosmet. Toxicol. Vol. 6, pp. 155–161. Pergamon Press 1968. Printed in Great Britain

Toxic Properties of Nordihydroguaiaretic Acid

H. C. GRICE, G. BECKING and T. GOODMAN

Research Laboratories, Food and Drug Directorate, Department of National Health and Welfare, Tunney's Pasture, Ottawa 3, Ontario, Canada

(*Received 19 January 1968*)

Abstract—Nordihydroguaiaretic acid (NDGA) fed to rats at levels of 0·5 or 1·0% in the diet for 74 wk caused cystic reticuloendotheliosis of paracaecal lymph nodes and vacuolation of kidney tubular epithelium. The o-quinone derived from NDGA was isolated from kidney tissue and identified by thin-layer chromatography and ultraviolet spectroscopy. Rats fed 2% NDGA in the diet for shorter periods of time exhibited similar pathological changes.

The o-quinone was formed from NDGA in the lower third of the ileum and caecum and was probably absorbed at that point. Urine samples from rats fed 2% NDGA contained the o-quinone but no free NDGA.

INTRODUCTION

Nordihydroguaiaretic acid (NDGA), 2,3-dimethyl-1,4-bis(3,4-dihydroxyphenyl)butane (Fig. 1) is a white crystalline solid prepared from an evergreen desert shrub, *Larrea divaricata*. It has been used as an antioxidant in foods.

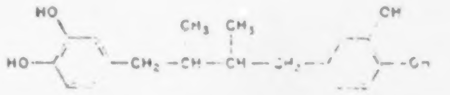

FIG. 1. Structural formula of nordihydroguaiaretic acid (NDGA).

Two-yr toxicity tests with male rats given 0·1–1% NDGA in the diet showed that 0·5% was the lowest level causing inflammatory caecal lesions and slight cystic enlargement of paracaecal lymph nodes (Lehman, Fitzhugh, Nelson & Woodard, 1951). Growth inhibition occurred after the first 6 months at levels of 0·5 and 1·0% NDGA. In another experiment, 0·5% NDGA in the diet caused massive caecal haemorrhages with single and multiple mesenteric cysts (Lehman *et al.* 1951).

Other workers (Cranston, Jensen, Moren, Brey, Bell & Bieter, 1947) stated that 0·5% NDGA had no marked effect on food intake, nor on the kidneys, liver and spleen. Dietary concentrations of 0·1, 0·5 and 1% NDGA were tested in another series of rats. Cysts in the mesentery were found in several animals given the higher concentrations of NDGA.

The Joint FAO/WHO Expert Committee on Food Additives (1962) reported:

> "From the limited information available, it is not possible to evaluate the toxicological status of NDGA. No guidance can therefore be given at present on the use of NDGA as an antioxidant in food."

A subsequent report (Joint FAO/WHO Expert Committee on Food Additives, 1965) again stated that available scientific evidence was "inadequate for evaluation" of NDGA.

The work reported here was undertaken to study the fate of NDGA and its metabolites in the rat in order to provide information on its safety for use as an antioxidant.

EXPERIMENTAL

Animal studies. Sixty weanling Wistar-derived rats were divided into three comparable groups of 10 males and 10 females each and housed in individual cages maintained in an air-conditioned room kept at 72–74°F. One group received a control diet ('Master Fox Cubes', Toronto Elevators Limited) whereas the others received the control diet to which was added 0·5 or 1% NDGA.

After 74 wk on test, survivors were killed and autopsied. The organs of rats that died during the experiment, and of the survivors, were examined, weighed, fixed in 10% formol saline and examined histologically. A few of the animals that died during the experiment were not examined in this manner, because of advanced autolysis. Stains used were haematoxylin, phloxine and saffron for routine purposes and a haemoglobin-haemosiderin stain (Puchtler & Sweat, 1962).

Electron-microscopic examinations were made of kidneys from rats of the same strain fed a diet containing 2% NDGA. The rats were deeply anaesthetized with ether and the kidneys were perfused with physiological saline followed by 2% buffered glutaraldehyde. Small blocks of tissue were further fixed for 3 hr in 5% glutaraldehyde buffered to pH 7·2 with 0·1 M-phosphate buffer; they were then rinsed with 10 changes of 5 min each in 0·2 M-sucrose, buffered to pH 7·2 with 0·1 M-phosphate buffer and post-fixed for 2 hr in 1% osmic acid buffered to pH 7·2 with veronal acetate buffer. Tissues were dehydrated through acetone and embedded in epon. Sections were observed in a Siemens Elmiskop Ia electron microscope.

Reference standards. Reference standards of NDGA were obtained after recrystallization of the commercial food-grade antioxidant from dilute acetic acid (m.p. 183–184°C).

NDGA was oxidized to the o-quinone at pH 9 by aeration at room temperature of a solution of the antioxidant in 50% aqueous ethanol. The o-quinone structure and complete lack of hydroxyl groups in the oxidation product were indicated by infrared and nuclear magnetic resonance spectroscopy. Formation of a crystalline derivative with o-phenylenediamine further proved that the red-brown oxidation product was an o-quinone. Both the quinone (R_F 0·00) and recrystallized NDGA (R_F 0·55–0·60) were chromatographically homogeneous, as indicated by thin-layer chromatography (TLC) using benzene-ethanol (7:1, by vol.) as the developing solvent. All TLC analyses were carried out on Eastman Silica Gel Chromagrams (Eastman Kodak Co., Rochester, N.Y.) containing fluorescent indicator and activated for 30 min at 100°. Free NDGA was determined by the method of Nair and Vaidyanathan (1964) and also by TLC in benzene-ethanol (7:1, by vol.). NDGA and *o*-quinone standards were run on all TLC sheets. In benzene-ethanol (7:1, by vol.), the *o*-quinone remains at the origin and during the analysis of tissue extracts and urine samples it is removed from pigmented material at the origin by re-development of the sheet in 0·01 N-NaOH in 70% ethanol (quinone R_F 0·95). The quinone was eluted with 50% aqueous ethanol and re-run using chloroform followed (after air drying) by benzene-ethanol (7:1, by vol.). The material remaining at the origin was eluted with 50% aqueous ethanol and examined by ultraviolet spectroscopy. In all quantitative analyses, the desired spots were eluted with 50% ethanol and the optical density was read at 210 mμ against a blank eluted from an equivalent area of the TLC sheet.

Biochemical studies. Biochemical investigations were carried out on selected tissues from the 74-wk study as well as on tissues from rats fed 2% NDGA. Fasted male Wistar rats weighing 200–250 g were used in studies designed to examine *in vivo* oxidation of NDGA. These rats were anaesthetized with nembutal and a midline incision was made to expose the duodenum. A tube was passed through the stomach into the duodenum, and a slurry of recrystallized NDGA (250 mg) in isotonic KCl was injected through the tube into the duodenum and jejunum. The tube was removed and the abdominal incision sutured. The rats were killed at varying time periods up to 7·5 hr. the contents of the small intestine were placed in 15 ml 70% aqueous ethanol and the flask was flushed immediately with nitrogen. In addition, the caecal contents from rats killed after 7·5 hr were also extracted.

Tissue samples were homogenized in 70% ethanol (15 ml/g tissue) for 1 min in a Sorvall omni-mixer. The homogenate was heated under reflux on a steam bath for 30 min and the residue removed by centrifugation and washed once with hot 70% ethanol (5 ml/g tissue). The combined supernatants were taken to dryness on a steam bath under nitrogen and dissolved in a minimum volume of 70% ethanol for determination of NDGA and its quinone metabolite. The remainder of the quinone, not extractable with aqueous ethanol, was extracted with 0·01 N-NaOH in 70% ethanol as outlined above.

Samples of intestinal contents were extracted under nitrogen for 1 hr on a steam bath. The hot suspension was filtered, the precipitate was washed with 10 ml hot 70% ethanol and the combined extracts were taken to dryness *in vacuo* at 40°C. The brown residue was washed with chloroform (2 × 25 ml) and acetone (2 × 25 ml). The semi-dried material was collected by filtration and dissolved in 50% ethanol for analysis.

The large quantities of pigments present in samples of intestinal contents necessitated the following TLC purification procedure. Extracts were placed as streaks on activated 20 × 20 cm chromatogram sheets and developed with *n*-butanol–acetic acid–water (4:1:1, by vol.). The material running with the quinone standard (R_f approx. 0·9) was eluted and re-run in benzene–ethanol (7:1, by vol.). After air drying, a final development with acetone was carried out prior to elution of the material remaining at the origin.

All spectra were determined on a Spectronic 502 spectrophotometer.

Urine samples from NDGA-treated and control rats were collected under toluene and 1 ml concentrated HCl and extracted on the day of collection. Prior to the extraction of NDGA and its metabolite, it was necessary to remove urinary pigments by successive washing with 4 vol. of the following solvents: chloroform (once), diethyl ether (twice) and ethyl acetate (twice). The extracted urine samples were taken to dryness, suspended in 0·5 ml water and filtered through glass wool, and absolute ethanol (4 vol.) was added to remove inorganic salts. The ethanol supernatant was saved for TLC analysis. A brown, sticky material adhering to the sides of the centrifuge tubes was dissolved in 50% ethanol for analysis.

RESULTS

Animal studies

There was no significant difference in food intake between control and treated groups throughout the course of the 74-wk study. Individual reductions in food intake were always attributable to intercurrent disease, such as pneumonia or advanced hydronephrosis, or to excessively long teeth that interfered with prehension.

The average body weights, kidney weights and kidney weight to body weight ratios are summarized in Table 1. Mean body weight gain was consistently lower in animals given NDGA than in the control group throughout the course of study. This effect was significant at wk 74. NDGA did not affect absolute kidney weights, but significantly influenced the kidney weight to body weight ratio (Table 1).

Table 1. *Average terminal body weight and absolute and relative kidney weights of rats fed NDGA at 0–1% of the diet for 74 wk*

Dietary level (%)	No. of rats	Terminal body weight (g)	Kidney weight: Absolute (g)	Kidney weight: Relative (g/100 g body weight)
		Males		
0	8	395	2·82	0·71
0·5	8	335**	2·75	0·82**
1·0	7	322**	2·65	0·82**
		Females		
0	6	270	2·31	0·86
0·5	9	[illegible]	[illegible]	0·95*
1·0	9	[illegible]	2·36	1·03*

*Values marked with asterisks differ significantly from those of controls: *$P<0·05$; **$P<0·01$.

Gross pathology

Thirteen of 60 rats on test died before wk 74. Deaths were nearly equally distributed between control and treated groups. The cause of death was usually related to endemic disease involving the respiratory, urinary or gastro-intestinal systems. At wk 74, cysts of the mesenteric lymph nodes (Fig. 2) at the ileocaecal junction were seen in 32 of 33 animals on NDGA. The cysts appeared to be equally distributed in all groups and between sexes. In one animal, in addition to a cystic structure, the nodes were involved by a malignant reticulum cell sarcoma.

Histopathology

Lymph nodes. There was cystic enlargement of the mesenteric lymph nodes with compression atrophy of cellular lymphoid elements (Fig. 3). Distortion and loss of normal nodal architecture was evident (Fig. 4) with replacement of the mid-region of germinal centres by foamy macrophages (Fig. 5). Cysts of varying size were present in affected nodes. Generally the cysts were not lined by a membrane but were bordered by cells of the lymphocytic series and foamy reticulo-endothelial cells. In some cystic spaces, there were islands of lymphocytes joined by loose connective tissue bridges in which numerous lymphocytes, plasma cells and macrophages were seen.

Phagocytic cells of two types were abundant. Cells of the first type had a foamy pink to grey cytoplasm. The nuclei were solid-faced with an indistinct chromatin network. These cells were actively phagocytizing red blood cells lying free in dilated sinuses. The other type of cell tended to occur in clusters or islands. In some areas these replaced cells of the germinal centre and were surrounded by a halo of lymphocytes (Fig. 6). Their cytoplasm was yellow-brown or contained brown granular material and their nuclei tended to be small and irregular. The overall histological picture in the lymph nodes was one of a cystic reticulo-endotheliosis.

Kidneys. The kidney diseases present included hydronephrosis, chronic pyelonephritis and nephrocalcinosis. In rats receiving NDGA there was vacuolation of the cortical tubular epithelium, particularly of the proximal convoluted tubules (Figs 7 & 8). The epithelial cellular outlines were indistinct and the cells swollen, so that the tubular lumen was very narrow or obliterated. The cytoplasm appeared pale and granular (Fig. 9) and the nuclei condensed. Many affected cells contained a finely granular pale-yellow material, which was lighter in colour and had a particle size smaller than haemosiderin. It was also negative to the haemosiderin stain (Fig. 10).

These distinctive tubular changes were seen in 17 of 18 rats on the 0·5% level and all 16 rats on the 1% level of NDGA, with no significant difference in incidence between sexes. The changes were not present in control rats.

The kidneys from rats fed 2% NDGA had widespread lesions and were thus suitable for electron-microscopic examination. Preliminary electron-microscopic studies indicated hydropic changes in the tubular epithelial cells, tubular necrosis, an abundance of lysosomes in some tubular cells (Fig. 11) and the occurrence of giant lysosomes in others (Fig. 12). Macrophages containing a granular material were numerous, appearing singly (Fig. 13) and in aggregates throughout the cortex. They were seen by light microscopy in the lymph nodes but not in the kidney of the rats given NDGA for 74 wk.

Biochemical studies

No free NDGA was found in lymph or kidney extracts after long- or short-term feeding studies. The small amount of lymphatic tissue available precluded positive identification of quinone metabolite in this tissue although a yellow-brown pigment was extracted which possessed similar properties to the standard *o*-quinone during TLC.

The quinone metabolite was found in all kidney extracts from rats fed 0·5 or 1% NDGA for 74 wk and had the same spectral and TLC characteristics as the standard *o*-quinone. No *o*-quinone was present in extracts from control rats. The extract prepared from kidney tissue taken from one rat fed 1% NDGA for 74 wk was found to contain red-brown quinone at a level of 300 μg/g tissue.

After short-term feeding studies (2% NDGA for less than [illegible] days), no evidence of free NDGA was obtained in test animals, but no attempt was made to assay for the presence of NDGA conjugates (glucuronide, ethereal sulphate etc.). The first trace of the *o*-quinone metabolite was found in kidney extracts from rats fed 2% NDGA for 28 days. After 80 days on test, 260 μg *o*-quinone/g kidney tissue was extracted.

24-Hr urine samples collected from rats fed 2% NDGA for 36 days contained no detectable free NDGA but did contain up to 56 μg of *o*-quinone. Urine samples from control rats contained no detectable free NDGA or quinone metabolite.

The formation of *o*-quinone in the rat intestine, after administration of NDGA directly into the small intestine, was determined at various times and the results are summarized in Table 2. After 6 hr, the NDGA had reached the vicinity of the ileocaecal junction and after 7·5 hr some had entered the caecum. It is evident that a significant amount of *o*-quinone is formed only after NDGA reaches the region of the ileocaecal junction.

Table 2. *Formation of o-quinone metabolite in the ileum and caecum of rats from a single dose of 250 mg NDGA*

	Analysis of contents of						
	Ileum						Caecum
Time after dosing (hr)	0	1	2	4	6	7·5	7·5
o-Quinone (μg)	0	0	Trace	6	480	2760	1620

DISCUSSION

The lesions of principal interest were those in the mesenteric lymph-nodes and kidney. NDGA was readily converted to its o-quinone metabolite in the lower third of the ileum and in the caecum. This is apparent from the chemical studies and from the fact that the lesion affected the lymph nodes draining this region of the intestine.

The quinone formed in the intestine is the probable source of the red-brown material found in the lymph-node cysts. Previous studies (Tauber, 1952; Tappel & Marr, 1954) on the inhibition of catalase by NDGA and the subsequent formation of o-quinone suggest that the quinone found in the kidney tissue could arise either from the intestine, or by production of quinone in the liver from NDGA absorbed in unchanged form. Since no free NDGA was found in rat tissue, it is probable that the o-quinone was derived principally from that formed in the lower third of the ileum and the caecum.

In the lymph nodes it was apparent that reticulo-endothelial cells were proliferating and actively phagocytizing foreign material. The cells displaced and replaced normal lymphoid structures and thereby apparently altered the morphology and function of the nodes. The macrophages became lodged or fixed in the cortical and medullary sinuses and multiple small cysts were formed as a result of distension of sinuses with lymph fluid unable to flow normally through the blocked passages.

Initially the cysts were small and contained pink-staining acellular material. With time, they tended to unite or coalesce to form large cysts that contained several ml of fluid.

The phagocytic cells in the lymph-nodes were represented by two apparently distinct types. The cells seen in the primary nodules were compacted by the restrictions of surrounding follicle cells or of the fine network of the reticular mesh in these areas. The phagocytic cells in the coarse mesh or distended sinuses were, on the other hand, less confined and were free-lying or loosely arranged. Both types of cell were actively phagocytizing haemosiderin as well as the yellow granular material that was probably NDGA or its quinone. The cells in the loose mesh work may have been more actively engaged in erythrophagocytosis merely because of their proximity to the red blood cells that were abundant in the coarse mesh of the nodal sinuses. The paracaecal lymph nodes in rats given NDGA responded to the insult by proliferating actively phagocytic reticulo-endothelial cells, which interfered with lymph flow and thus led to the formation of cysts.

It is apparent that some quinone passed the caecal lymph-node barrier or entered the body by way of the blood stream and eventually gained access to the kidney. Allowing for the chronic changes normally seen in rats of this age, the glomeruli appeared normal. The quinone also passed the capillary barrier of the glomeruli and was reabsorbed by the epithelial cells of the proximal convoluted tubules, for some quinone was retained in the tubular epithelial cells and was identified histologically and chemically. When NDGA was fed at a level of 2% in the diet, the quinone appeared in the urine. It is likely therefore that any NDGA or metabolite not reabsorbed by the proximal convoluted tubules was eliminated in the urine. The histological peculiarities of the rat kidney would support this view, since tubular changes appeared to be confined to tubules in the outer cortex and in the rat these are principally proximal convoluted tubules.

Kidney-weights in NDGA-treated animals were significantly heavier relative to body weight than were their control counterparts. This might be expected if the kidney underwent hypertrophy to compensate for loss of tubular function. Tubular cells were distended and appeared to occlude the tubular lumen. There must have been some degree of tubular patency however, since there was no evidence of fluid retention in the glomeruli. Furthermore, in rats fed 1% NDGA or less, atrophic tubular changes were not a prominent histological finding and on the basis of these observations it seems likely that tubular function was little affected.

It is apparent from these and previous studies that NDGA does not meet the criteria suggested for a safe food antioxidant (Dacre 1960).

Acknowledgements—We wish to thank Dr. D. F. Bray and Mr. D. A. Lyon for statistical assessment and [illegible] discussions which led to a better understanding of the pathogenesis of the lymph node and renal lesions. The work of Dr. George Neville who did the NMR analyses is very much appreciated as is the [illegible] and [illegible] of Drs. A. [illegible] and A. B. Morrison. Miss Z. Z. Zawidzka, Miss I. Dupuis and Mrs. N. [illegible] are thanked for their excellent technical assistance.

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Propriétés toxiques de l'acide nordihydroguaiarétique

Résumé—L'acide nordihydroguaiarétique (NDGA) administré dans le régime des rats à des teneurs de 0,5 ou 1,0% pendant 74 semaines a provoqué une réticulo-endothéliose cystique des ganglions lymphatiques mésentériques et une vacuolisation de l'épithélium tubulaire du rein. L'o-quinone dérivée du NDGA a été isolée à partir de tissu rénal et identifiée par chromatographie sur couche mince et spectroscopie à l'ultraviolet. Des rats recevant des régimes contenant 2% NDGA pendant une période plus courte ont présenté des anomalies pathologiques similaires.

L'o-quinone se forme à partir du NDGA dans le tiers inférieur de l'iléon et du caecum et est probablement absorbée en cet endroit. Des échantillons d'urines de rats recevant 2% de NDGA contenaient l'o-quinone mais pas de NDGA libre.

Toxische Eigenschaften von Nordihydroguajaretinsäure

Zusammenfassung—Nordihydroguajaretinsäure (NDGA), die an Ratten in Konzentrationen von 0,5 oder 1,0% im Futter 74 Wochen lang verfüttert wurde, verursachte cystische Reticuloendotheliose der paracaecalen Lymphknoten und Vacuolenbildung des Epithels der Nierenkanälchen. Das o-Chinonderivat der NDGA wurde aus dem Nierengewebe isoliert und durch Dünnschichtchromatographie und UV-Spektroskopie identifiziert. Ratten, die 2% NDGA für kürzere Zeit im Futter erhielten, zeigten ähnliche pathologische Veränderungen.

Das o-Chinon wurde aus NDGA im unteren Drittel des Ileum und Caecum gebildet und wahrscheinlich an dieser Stelle absorbiert. Urinproben von Ratten, die 2% NDGA erhielten, enthielten das o-Chinon, aber keine freie NDGA.

§ 811.65 Restrictions on importations and marketings within quotas.

Subject to the provisions of Parts 816 and 817 of this chapter, all persons are prohibited from bringing or importing into or marketing in the continental United States any sugar or liquid sugar in excess of or after the applicable quota or quantity set forth in §§ 811.61 to 811.63, inclusive, has been filled or any sugar or liquid sugar as direct-consumption sugar after the direct-consumption portion of the applicable quota has been filled.

Signed at Washington, D.C., this 17th day of November 1967.

JOHN A. SCHNITTKER,
Under Secretary.

[F.R. Doc. 67-13698; Filed, Nov. 21, 1967; 8:45 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

NORDIHYDROGUAIARETIC ACID

Proposed Removal From List of Substances Generally Recognized as Safe for Food Use

Nordihydroguaiaretic acid is listed in § 121.101(d)(2) of the food additive regulations (21 CFR 121.101(d)(2)) as a substance generally recognized as safe for use in food as a preservative. The Commissioner of Food and Drugs has considered the announced action of the Canadian Food and Drug Directorate proposing the banning of the additive for food use, and other relevant information, and concludes that nordihydroguaiaretic acid is no longer entitled to be classed as generally recognized as safe.

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(d), 72 Stat. 1787; 21 U.S.C. 348(d)) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.120), it is proposed that § 121.101 *Substances that are generally recognized as safe* be amended by deleting from paragraph (d)(2) the item "Nordihydroguaiaretic acid."

Any interested person may, within 30 days from the date of publication of this notice in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments, preferably in quintuplicate, on this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: November 13, 1967.

J. K. KIRK,
Associate Commissioner for Compliance.

[F.R. Doc. 67-13713; Filed, Nov. 21, 1967; 8:48 a.m.]

[21 CFR Part 148i]

NEOMYCIN SULFATE

Proposed Modification of Identity Method

Under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357) and delegated by him to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that § 148i.1 (a)(1)(vii) and (b)(7) and § 148i.22(a)(1)(v) be revised to read as follows to modify and improve the method of identity for the antibiotic neomycin sulfate:

§ 148i.1 Neomycin sulfate.

(a) * * *

(1) * * *

(vii) It gives a positive identity test for neomycin.

* * * * *

(b) * * *

(7) *Identity*—(i) *Reagents*—(*a*) Sulfuric acid solution: Mix concentrated sulfuric acid and distilled water in volumetric proportions of 40:60.

(*b*) Xylene.

(*c*) p-Bromoaniline: (Prepare and store this reagent in brown, nonactinic glassware.) Place 380 milliliters of thiourea-saturated glacial acetic acid solution in the bottle, add 10 milliliters of 20 percent sodium chloride solution, 5 milliliters of 5 percent oxalic acid solution, and 5 milliliters of 10 percent disodium phosphate solution, and mix well. Add 8.0 grams of p-bromoaniline and mix well. Let this reagent stand overnight before use. Prepare the reagent once weekly.

(ii) *Procedure.* Place about 10 milligrams of the sample into a test tube (19 millimeters x 150 millimeters), dissolved with 1 milliliter of water, and then carefully add 5 milliliters of the sulfuric acid solution. Heat in a boiling water bath for 100 minutes. Cool to room temperature. Add 10 milliliters of xylene to the test tube. Stopper the tube and shake vigorously for about 1 minute. Let the two layers separate and then decant the xylene layer into a second test tube. Add 10 milliliters of the p-bromoaniline reagent to the xylene solution, shake, and let stand. The development of a vivid pink-red color is a positive identity test for neomycin.

§ 148i.22 Neomycin sulfate for prescription compounding.

(a) * * *

(1) * * *

(v) It gives a positive identity test for neomycin.

* * * * *

Any interested person may, within 30 days from the date of publication of this notice in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments, preferably in quintuplicate, on this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: November 16, 1967.

J. K. Kir
Associate Commiss
for Comp

[F.R. Doc. 67-13714; Filed, Nov
8:48 a.m.]

[21 CFR Part 166]

DEPRESSANT AND STIMULANT

Proposed Listing of Addition as Subject to Control

The Commissioner of Food an
proposes, on the basis of his in
tions and the recommendation
advisory committee appointed
to section 511(g)(1) of the Fede
Drug, and Cosmetic Act, that
set forth below be listed as a "de
or stimulant" drug within the
of section 201(v) of the act be
its hallucinogenic effect. Therefo
suant to the provisions of the a
201(v), 511, 701, 52 Stat. 1
amended, 79 Stat. 227 et seq.; 2
321(v), 360a, 371) and under the
ity delegated by the Secretary of
Education, and Welfare to the
sioner (21 CFR 2.120), it is propo
§ 166.3(c)(3) be amended by al
cally inserting in the list of drug
item, as follows:

§ 166.3 Listing of drugs define tion 201(v) of the act.

* * * *

(c) * * *

(3) * * *

Established name	*Some trade or othe*
DOM (STP)	4-Methyl-2,5-dim amphetamine; 4 2,5-dimethoxy- methylphenethy and "STP".
* * *	* * *

* * * *

All interested persons are in
submit their views in writing re
this proposal. Comments concern
additional trade or other nam
may be properly listed for the
drug are also invited. Views ar
ments should be submitted, pr
in quintuplicate, addressed to th
ing Clerk, Department of Health,
tion, and Welfare, Room 5440, 33
pendence Avenue SW., Washingt
20201, within 30 days following
of publication of this notice in t
ERAL REGISTER, and may be accom
by a memorandum or brief in
thereof.

Dated: November 14, 1967.

JAMES L. GODD
Commissioner of Food and

[F.R. Doc. 67-13715; Filed, Nov 2
8:48 a.m.]

quested in a petition (FAP [illegible]) filed by Chas. Pfizer and Co., Inc., 235 East 42d Street, New York, N.Y. 10017, and other relevant material, has concluded that the food additive regulations should be amended to provide for the safe use of sulfomyxin for the injection of chickens and turkeys for conditions specified below. (In the notice of filing of said petition, published in the FEDERAL REGISTER of Apr. 7, 1966 (30 F.R. [illegible]), the additive was referred to as "polymyxin methane sulfonate," a proposed nonproprietary name; however, that nomenclature has not been adopted.)

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.120), Part 121 is amended by adding to Subpart C the following new section.

§ 121.318 *Sulfomyxin.*

The food additive sulfomyxin (*N*-sulfomethylpolymyxin B sodium salt) may be safely used in the treatment of animals in accordance with the following prescribed conditions:

(a) The additive is derived from the antibiotic substance produced by growth of *Bacillus polymyxa* or is the same substance produced by any other means.

(b) (1) It is sterile and it is used or intended for use in chickens and turkeys as an aid in the treatment of diseases caused or complicated by *E. coli*, such as colibacillosis and complicated chronic respiratory disease.

(2) It is administered by subcutaneous injection as follows:

Age of birds in days	Antibiotic activity	
	Chickens	Turkeys
	Units	Units
1 to 10	12,500	12,500
11 to 30	25,000	25,000
31 to 60	50,000	50,000
Over 60	50,000	100,000

(3) A second injection may be given 3 days later if symptoms persist.

(c) To assure safe use the label and labeling of the additive shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive.

(2) A statement of the quantity contained therein.

(3) Adequate directions and warnings for use including the statements:

(i) "Not for use in laying hens"; and

(ii) "Do not treat chickens within 5 days and turkeys within 7 days of slaughter."

2. Based upon an evaluation of the data before him and proceeding under the authority of said act (sec. 409(c)(4), 72 Stat. 1786; 21 U.S.C. 348(c)(4)), delegated as cited above, the Commissioner has concluded that tolerance limitations are required to assure that edible products from chickens and turkeys treated with sulfomyxin in accordance with § 121.318 are safe for human consumption. Accordingly, Part 121 is amended by adding to Subpart D the following new section:

§ 121.1277 *Sulfomyxin.*

A tolerance of zero is established for residues of sulfomyxin (*N*-sulfomethylpolymyxin B sodium salt) in edible tissues from chickens and turkeys.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(c) (1), (4), 72 Stat. 1786, 21 U.S.C. 348(c) (1), (4))

Dated: April 3, 1968.

J. K. KIRK,
Associate Commissioner for Compliance.

[F.R. Doc. 68-4430; Filed, Apr. 10, 1968; 8:48 a.m.]

PART 121—FOOD ADDITIVES

Subpart B—Exemption of Certain Food Additives From the Requirement of Tolerances

NORDIHYDROGUAIARETIC ACID; REMOVAL FROM LIST OF SUBSTANCES GENERALLY RECOGNIZED AS SAFE

A proposal to remove nordihydroguaiaretic acid (NDGA) from the list of substances generally recognized as safe for use in food as preservatives (21 CFR 121.101(d)(2)) was published in the FEDERAL REGISTER of November 22, 1967 (32 F.R. 16048). Comments received thereon from three interested parties provided no substantive evidence to alter the proposed course of action. It is entirely appropriate for any interested party to submit a food additive petition with data that establish the conditions of safe use for NDGA in food.

Removal of NDGA from the list of substances generally recognized as safe reclassifies this compound as a food additive for which a food additive regulation is necessary to permit its use. The existing food additive regulation for the use of NDGA in packaging material, § 121.2514, is not altered by this action nor is the existing prior sanction in certain other packaging uses as provided in § 121.2001(a). In the absence of a regulation providing for uses of NDGA directly in food, a proposal to remove NDGA from the list of permitted optional ingredients in the soda water standard is published elsewhere in this issue of the FEDERAL REGISTER.

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(d), 72 Stat. 1787; 21 U.S.C. 348(d)) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.120), § 121.101 *Substances that are generally recognized as safe* is amended by deleting from paragraph (d)(2) the item "Nordihydroguaiaretic acid."

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(d), 72 Stat. 1787, 21 U.S.C. 348(d))

Dated: April 1, 1968.

J. K. KIRK,
Associate Commissioner for Compliance.

[F.R. Doc. 68-4323; Filed, Apr. 10, 1968; 8:47 a.m.]

Title 22—FOREIGN RELATIONS

Chapter I—Department of State

[Dept. Reg. 108.583]

PART 41—VISAS: DOCUMENTATION OF NONIMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

Nonimmigrant Documentary Waivers

Correction

In F.R. Doc. 68-4183 appearing at page 5410 in the issue of Friday, April 5, 1968, the signature appearing at the end of the document should read "Raymond F. Farrell, *Commissioner of Immigration and Naturalization, Immigration and Naturalization Service, Department of Justice.*"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date JUN - 1 1984

From Associate Commissioner
for Regulatory Affairs (HFC-1)

Subject Foods and Cosmetics Promoted with Medical Claims

To Regional Food and Drug Directors
District Directors
Directors, Field Compliance Branches
Center for Drugs and Biologics
Center for Food Safety and Applied Nutrition

In order to implement the recommendations of the vitamin/mineral task force, the agency issued field management directive 131 on January 12, 1983. That document directed the field to submit any regulatory action concerning a human vitamin/mineral product to the Center for Food Safety and Applied Nutrition (formerly the Bureau of Foods), regardless of the proposed charges. It has become apparent during the past year that the recommendations of the task force did not contemplate the type of products we are encountering with increasing frequency.

In an effort to deal with the current situation, the Center for Drugs and Biologics and the Center for Food Safety and Applied Nutrition met with the Director, Enforcement Policy Staff, and the Office of General Counsel on March 7, 1984. It was agreed that food products now being encountered, which are promoted for the treatment of serious disease conditions (without the required proof of safety and effectiveness), shall be considered new drugs. Vitamin/mineral supplements promoted for disease conditions are not exempt from regulatory action by section 411. Accordingly, these products come under the jurisdiction of the Center for Drugs and Biologics.

Therefore, effective immediately, field management directive 131 is cancelled. All recommended regulatory actions against food products represented as foods, dietary supplements, or cosmetics but labeled or otherwise offered for therapeutic claims should be submitted to the Center for Drugs and Biologics. Regulatory action against such products will normally be brought under the drug and/or new drug provisions of the act. A memo concerning our internal review procedures and the agency's views on relabeling, reconditioning, etc., will issue in due course. For the present, the Center for Drugs and Biologics will promptly review and render a decision on all cases presently pending in either center that have been held pending a decision on this matter.

Any turndown by the center will be submitted to the Compliance Policy Council in accordance with the health fraud initiative.

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